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(54) **Improvements in or relating to surgical forceps for applying clips to Fallopian tubes**

(57) This invention relates to surgical forceps for applying clips to Fallopian tubes. The forceps comprises a stem 1 having an excision 1*a* at its distal end for insertion of a clip 3 formed by two branches held apart by an elastic connecting strap comprising a closing lever 12, 19 displaceable in the stem axially with respect to the clip by means of a proximal handle 23, 25, and situated in the area of the stem excision, which by actuation of said handle is pivoted into the closed position and brings the free extremity of the clip branches into coupled engagement gripping one behind the other in hooklike manner. In this invention a cylindrical sleeve 53 is provided which is arranged to be pushable axially over the forceps stem from the distal extremity, which brings or pivots the unclosed branch of the inserted clip 3 projecting from the periphery of the forceps stem in the excised portion 1*a* of the stem 1 against the other clip branch held fast in the forceps without coupled engagement into a position in alignment with said forceps stem, the stem being insertable through a trocar sleeve 51.

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FIG. 1

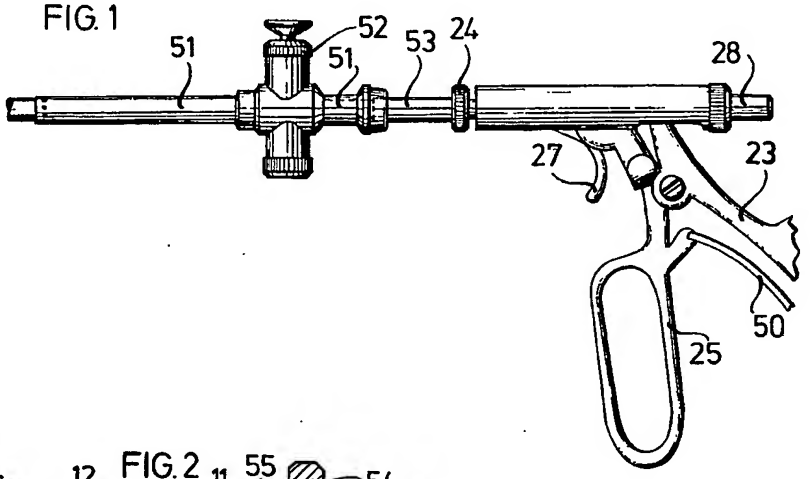
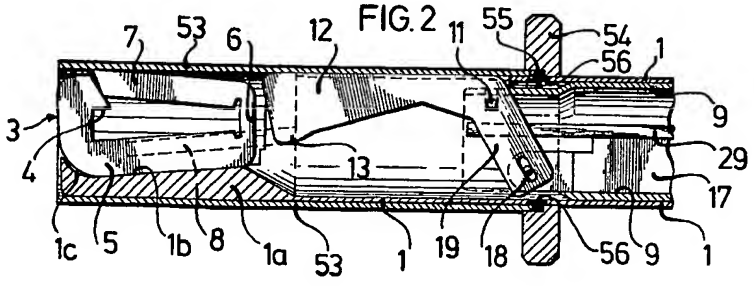


FIG. 2



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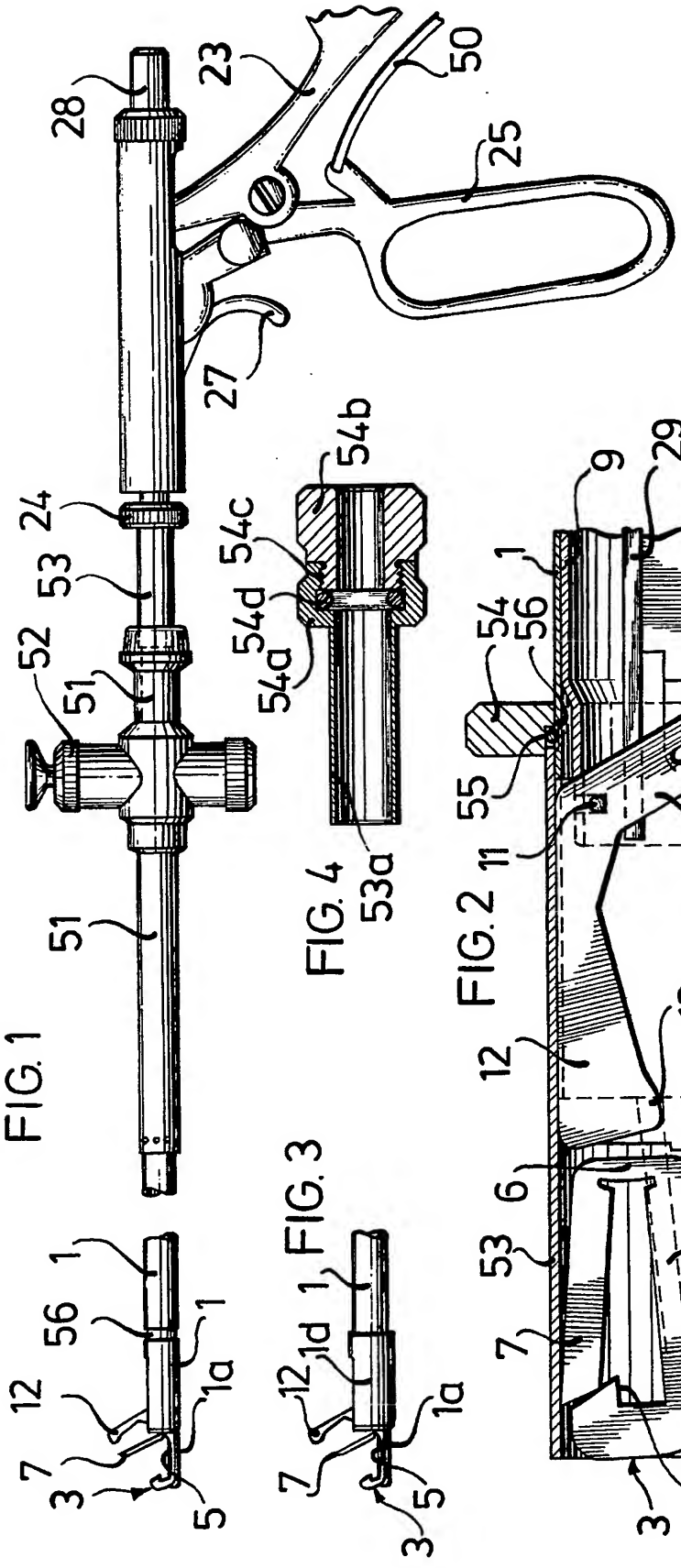

FIG. 1

FIG. 4

FIG. 3

FIG. 2

SPECIFICATION

Improvements in or relating to surgical forceps for applying clips to fallopian tubes

The present invention relates to surgical forceps for applying clips to Fallopian tubes, of the kind comprising a stem having a excision at its distal end for insertion of a clip formed by two branches held apart by an elastic connecting strap and comprising a closing lever displaceable in said stem axially with respect to said clip by means of a proximal handle and situated in the area of said stem excision, which by actuation of said handle is pivoted into the closed position and brings the free extremities of said clip branches into coupled engagement gripping one behind the other in hooklike manner. Hereinafter, such forceps will be referred to as "of the kind described".

Known forceps of the aforesaid kind e.g. those described in copending British patent specification 2027633A are so constructed that the clip inserted into the forceps aperture has its branches spread open at the distal side by virtue of resilient construction. For application of clips on Fallopian tubes, such forceps must be inserted through a trocar sleeve transpiercing the abdominal wall. The unclosed clip should concomitantly and evidently be placed in a position in which it may be pushed through the trocar sleeve, i.e. the unclosed position should be reversed, but the clip branches may not as yet have their free extremities coupled in mutual engagement. To this end, the double-armed closing lever of the forceps aperture has the lever arm which acts against the unclosed clip branches formed in a particular manner. For insertion of the clips, the closing lever should first be opened and then closed after insertion of the clip, in order to place the unclosed clip branch into the position in alignment with the trocar sleeve. After the clip is passed through the trocar sleeve, the closing lever and thus the clip should be opened again by actuation of the forceps handle, so that said clip may be laid around the Fallopian tube, whereupon the forceps aperture is pushed forward by the forceps handle and the closing lever is finally pivoted into the closed position, in which the two free extremities of the clip branches are coupled in mutual engagement in hook-like manner.

It is an object of the invention to render it possible to utilise a particular uncomplicated closing lever of the clip forceps, and to ensure that the closing lever need merely be actuated for closing the clip branches into the coupled position by means of the forceps handle, thus simplifying the operation of the forceps.

Accordingly, the invention consists in a surgical forceps of the kind described, wherein a cylindrical sleeve is provided which is arranged to be pushable axially over the forceps stem from the distal extremity, which brings or pivots the unclosed branch of the inserted clip projecting from the periphery of the forceps stem in the excised portion of the stem against the other clip branch held fast in the forceps without coupled engagement into a position in alignment with the forceps stem insertable through a trocar sleeve.

By virtue of this solution, the clip inserted into the forceps aperture has its branch spreading out of the excision pivoted by the cylindrical sleeve which may be pushed over said aperture into a position in which the unclosed clip branch is aligned with the forceps stem, the closing lever adjacent to the clip at the proximal side being held in the closed position by means of a spring-loaded forceps handle. Whilst the forceps stem bearing the cylindrical sleeve on the distal extremity is being inserted into the ventral cavity through a trocar sleeve, the cylindrical sleeve is held back at the proximal side either in or in front of the trocar sleeve. The branch of the clip which then opens out a little is then placed against the inner surface of the trocar sleeve and, after the forceps stem emerges from the distal extremity of the trocar sleeve, the clip branch projects out of the forceps stem, so that the forceps stem may be guided under observation in controlled manner and may be pushed with the spread-open clip over a Fallopian tube. The closing lever is thereupon opened by means of the proximal handle of the forceps and is moved forwards towards the distal side until the closing lever is situated in the area of the unclosed clip branch. By another actuation of the forceps handle or spring action of the released pivotable handle lever, the closing lever is closed and the unclosed clip branch is thereby also pivoted and coupled in mutual engagement with the other clip branch.

In order that the invention may be more clearly understood, reference will now be made to the accompanying diagrammatic drawings, which show certain embodiments thereof by way of example and in which:—

Figure 1 shows the forceps for application of a clip on a Fallopian tube after being led in through a trocar sleeve, in sideview,

Figure 2 shows the distal extremity of the clip forceps comprising a cylindrical sleeve, prior to inserting the clip and the forceps through the trocar sleeve, in axial cross-section,

Figure 3 shows a modified distal extremity of the clip forceps in sideview, and

Figure 4 shows an axial cross-section through a cylindrical sleeve modified as compared to Fig. 2, for application on forceps incorporating the modification according to Figure 3.

Referring now to the drawings, the clip forceps in accordance with the invention is of the general kind described in principle in British patent specification no 2027633A hereinabove referred to. The reference symbols of this published specification have consequently been adopted for corresponding parts of the present invention.

The forceps for application of a clip 3, consisting of elastic plastics material for example, comprises a cylindrical stem 1 which is excised at one side at the distal extremity and thereat forms a seat 1*b*, 1*c*, at 1*a* for insertion of a clip 3 which comprises a branch 5 comprising a coupling hook 4 secured in the seat 1*b* 1*c*, and a resilient connecting strap 6 for opening the branch 7, and which is retained in the seat by means of lateral projections 8 which bear against lateral

flanges of the immobilised branch 5. The open position of the clip 3 is illustrated in Figure 1. The seat 1*b*, 1*c* is followed at the proximal side by a two-armed closing lever comprising the arm 12 having the projection 13 and the arm 19. The two-armed lever 12, 19 is carried at 11 in the distal extremity of a cylinder 9 which is displaceable axially towards the distal end in the forceps stem 1 against a spring which is not illustrated and through which extends a linkage 17 which is coupled pivotally with a joint at the distal side to the closing lever arm 19 at 18, and which may be displaced at the proximal side by a spring-loaded arm 23 of a forceps handle towards the distal end with respect to the cylinder 9. The forceps lever 23 is pivotally jointed to the forceps lever 25 and is loaded by a spring 50 with respect to the lever 25. By compressing the forceps handle 23, 25, against the spring 50, the closing lever 12, 19 is retracted towards the proximal side under simultaneous actuation of the handle lever 27 by means of the cylinder 9 and of the linkage 17, and the closing lever 12, 19 is initially placed into a position parallel to the axis of the stem, which is initially retained. In this position of the closing lever according to Figure 2, the clip 3 is spread open however by its intrinsic elasticity.

For application of the clip 3 on a Fallopian tube, said clip should then be inserted by means of the forceps through a trocar sleeve 51 comprising a "trumpet" valve 52 and extending through the abdominal wall of the patient. To this end, the spread clip 3 should be placed in a position in which the unclosed branch 7 lies flush with the internal surface of the trocar sleeve 51, and the closing lever 12, 19 should be placed in the closing position according to Fig. 2 by manipulation.

To accomplish this in uncomplicated manner, a cylindrical sleeve 53 which retains the pushed-back clip branch 7 in the position according to Fig. 2 is pushed over the distal-side extremity of the forceps stem 1 whilst pushing the unclosed clip branch 7 back into the position according to Fig. 2 in which the clip branches do not however as yet have their free extremities caught one in the other or coupled to each other. This cylindrical sleeve 53 is concomitantly grasped at the proximal side by an annular flange 54 and is endowed in the area of the flange 54 with an inner annular groove into which fits a springy split ring 55 which when the sleeve 53 is pushed on engages in a shallow external annular groove 56 of the forceps stem 1 and holds the sleeve 53 fast against axial displacement on the stem 1 with slight spring force.

In this arrangement of the forceps, the distal forceps extremity carrying the cylindrical sleeve 53 is inserted into the proximal extremity of the trocar sleeve 51 having a greater internal diameter than the cylindrical sleeve 53, until the annular flange 54 is held back by the proximal terminal extremity of the trocar sleeve 51 or in case of the outer diameter of the cylindrical sleeve 53 being greater than the inner diameter of the trocar sleeve 51, the distal extremity of the cylindrical sleeve bears against the proximal end side of the trocar sleeve. By axial pressure, the spring ring 55 engages in the shallow peripheral groove 56 of the forceps stem 1, so that upon pushing the forceps 1 onwards towards the distal side, the cylindrical sleeve 53 is displaced in or in front of the proximal extremity of the trocar sleeve on the forceps stem which also passes through the trocar sleeve, the clip branch 7 also opening a little and sliding along the inner surface of the trocar sleeve 51 until it may expand again into the open position at the outer distal extremity of the trocar sleeve 51, as shown in Fig. 1.

In this position, the clip may be offered up to the Fallopian tube in conventional manner under observation, by means of the forceps, and pushed over the Fallopian tube.

As soon as the clip 3 and the closing lever 12, 19 have passed through the trocar sleeve 51, the forceps or the closing lever may be opened again within the bodily cavity by spreading the two forceps handles 23, 25 apart, the closing lever 12, 19 being displaced to the distal extremity by the spring 50 of the forceps handle and then assumes the position shown in Fig. 1. After the clip 3 had been pushed over the Fallopian tube, the closing lever 12 is pivoted against the clip branch 7 by compression of the forceps handle 23, 25 against the spring 50, and this branch 7 is pushed until the free extremity of the branch 7 engages behind the hook 4 of the clip branch 5. The closing lever 12, 19 is then pivoted so that the clip clamped over the Fallopian tube is ejected from the forceps by means of the ejector rod 29, by actuation of the proximal-arranged mechanism 28. After ejection, the closing lever 12, 19 is again placed in the position shown in Figure 2 and the forceps may then be pulled towards the proximal side through the trocar sleeve 51 and out of the bodily cavity.

Instead of the cylindrical sleeve 53 according to Figure 2, it is also possible to apply a cylindrical sleeve 53*a* according to Figure 4, but this presupposes that the forceps stem 1 is increased in diameter in stepped manner as compared to that of the stem 1, along the distal length 1*d*, according to Figure 3. The internal diameter of the cylindrical sleeve 53*a* according to Figure 4 is increased accordingly. Proximally this cylindrical sleeve 53*a* has a connector 54*a* which, with respect to the internal diameter of the sleeve 53*a*, is equipped by virtue of a step with an outwardly displaced axially directed internal screwthread. Into this internal screwthread may be screwed the external screwthread of a cylindrical ring 54*b* the internal diameter of which is smaller than the internal diameter of the cylindrical sleeve 53*a* and corresponds to the external diameter of the forceps stem 1. An elastic O-ring 54*d* which may be deformed by the ring 54*b* which may be screwed in, is inserted between the mutually opposed end sides of the connector step and of the cylindrical ring 54*b*.

The ring 54*b* remains on the stem 1 constantly, whereas the cylindrical sleeve 53*a* and the connector 54*a* which may be pushed on to the stem extremity 1*d* from the distal-side end to place the clip 3 in the position according to Figure 2, may be screwed on to the external screw-thread of the cylindrical ring 54*b*, the distal extremity of the ring 54*b* bearing against the step of the stem extremity 1*d* and being held fast by friction by means of the deformed annular spring

54*d*. By unscrewing the parts 53*a*, 54*a* on the one hand and 54*b* on the other hand, from each other, the sleeve 53 may be pulled off the forceps stem and sterilised. When the forceps comprising the stem 1, 1*a* and with a clip in the position according to Figure 2 is to be inserted into the ventral cavity via a trocar sleeve 51, the distal extremity of the sleeve 53*a* is placed against the proximal extremity of the trocar sleeve 51 and held back under axial pressure on the forceps directed towards the distal side. The cylindrical sleeve 53*a* is also displaced slidingly under friction on the stem. As soon as the forceps emerge from the distal extremity of the trocar sleeve, the springy clip 3 spreads open as already described with reference to Figures 1 and 2.

CLAIMS

1. A surgical forceps of the kind described, wherein a cylindrical sleeve is provided which is arranged to be pushable axially over the forceps stem from the distal extremity, which brings or pivots the unclosed branch of the inserted clip projecting from the periphery of the forceps stem in the excised portion of the stem against the other clip branch held fast in the forceps without coupled engagement into a position in alignment with the forceps stem insertible through a trocar sleeve.

2. Forceps as claimed in claim 1, wherein the cylindrical sleeve is displaceable axially on the forceps stem and has an external annular flange at its proximal end, and also has an outer diameter which, with impingement of said annular flange against the proximal end face of the trocar sleeve, fits into the proximal extremity of the trocar sleeve or is greater than the internal diameter thereof.

3. Forceps as claimed in claim 1 or 2, wherein the cylindrical sleeve is provided with a split spring ring that fits into an internal annular groove, which, when the clip is inserted, is overlapped by the cylindrical sleeve, and engages partially into a shallow outer annular groove in the forceps stem.

4. Forceps as claimed in claim 1, wherein the distal extremity of the stem is enlarged in diameter and the cylindrical sleeve has a connector which, with respect to the internal sleeve diameter and by means of a step, is provided with an outwardly-displaced axial internal screw-thread into which the external screw-thread of a cylindrical ring is screwable, the internal diameter of which ring corresponds to the outer diameter of the forceps stem, and wherein an O-ring acting as a seal is clampable between the step of the connector and the ring.

5. A surgical forceps for applying clips to Fallopian tubes substantially as hereinbefore described with reference to the accompanying drawings.

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(51) INT CL⁴
D05B 23/00 A61B 17/04

(52) Domestic classification
D1G AA F MA
A5R EW
B4C 104 A2 B7 B9
U1S 1027 1067 B4C

(56) Documents cited
GB A 2085934
GB A 2050448
GB 0461673
US 4484580

(58) Field of search
D1G

(54) Sewing or stapling machine

(57) A sewing machine for forming stitches in a substrate (16, 116), for example in forming stitches in tissue during surgery, comprises a needle (6; 106; 20, 30) for passing thread (9, 109, 24) into the substrate from one side thereof at a first location and for withdrawing the thread from the substrate at a second location spaced from the first location. The needle is removably operable solely from the said one side of the substrate. A stapling machine is also disclosed operating on similar principles for similar purposes.

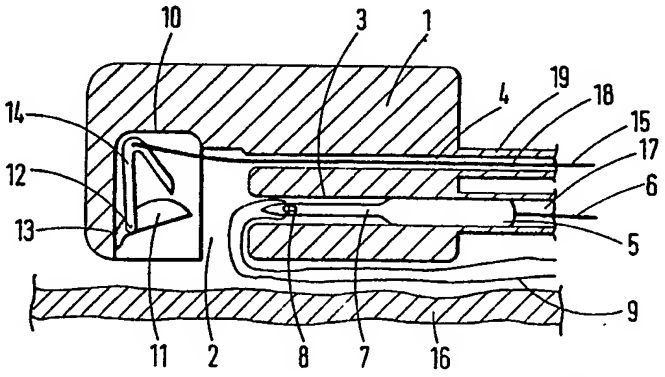

Fig.1a

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The drawings originally filed were informal and the print here reproduced is taken from a later filed formal copy.

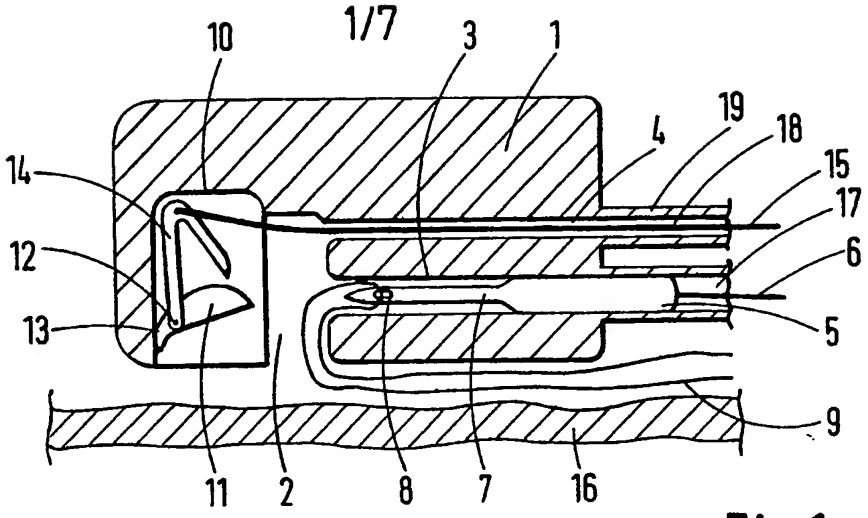


Fig.1a

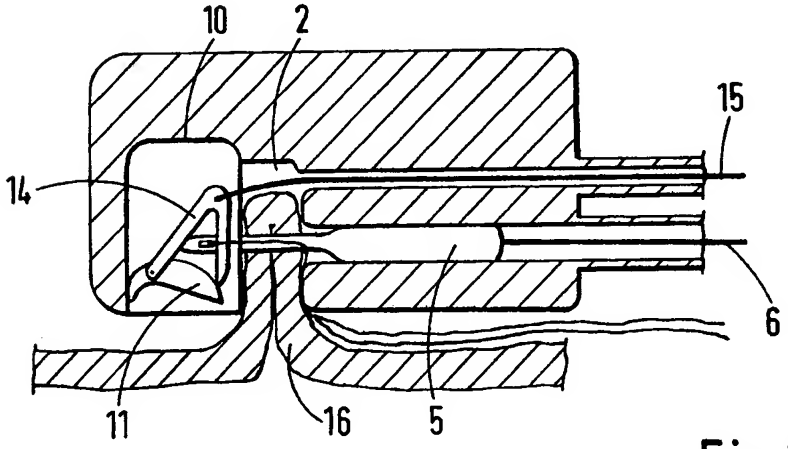


Fig.1b

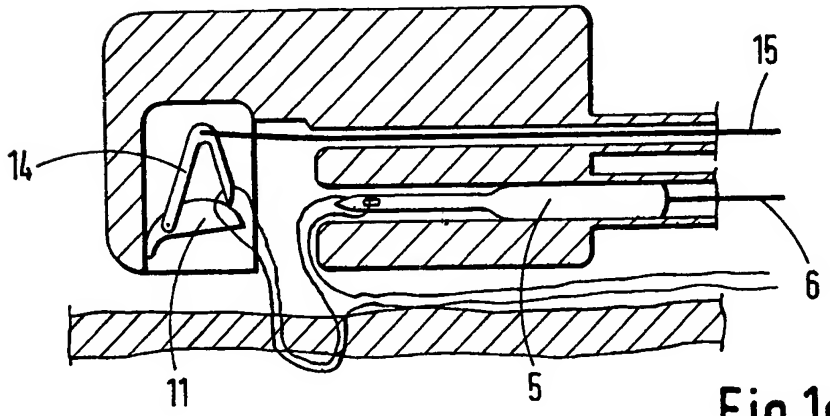


Fig.1c

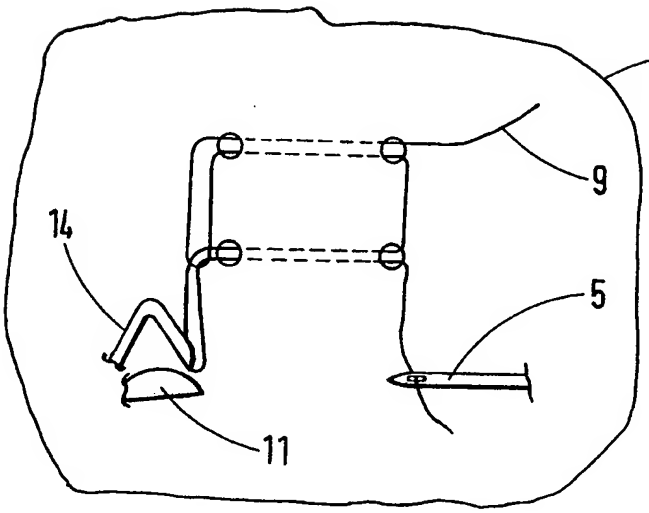


Fig.2

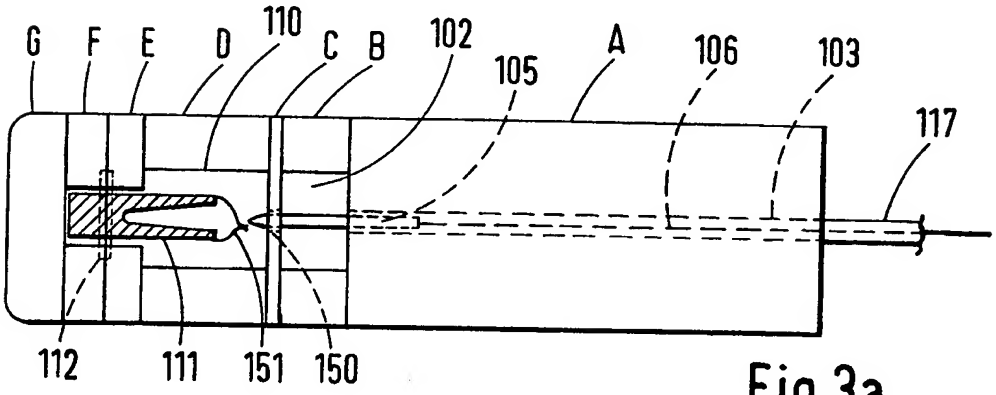


Fig.3a

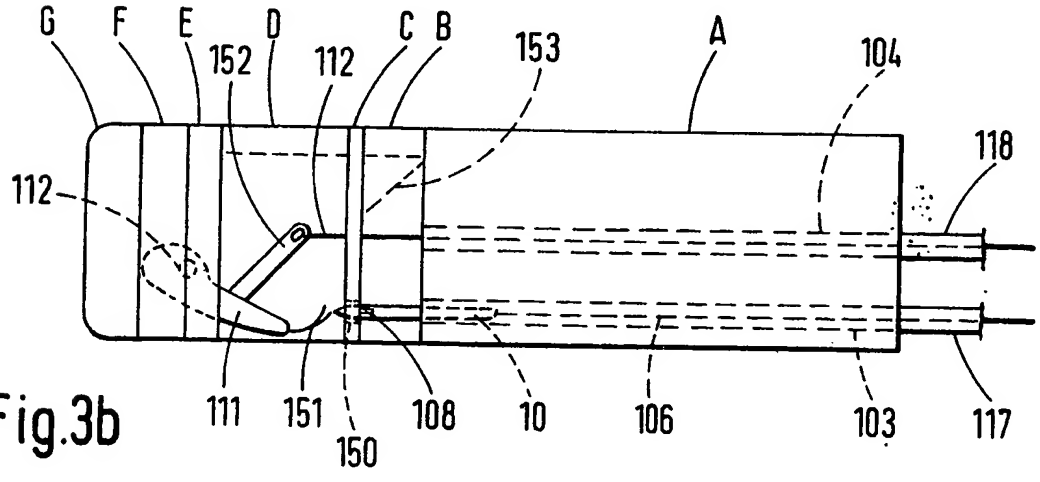


Fig.3b

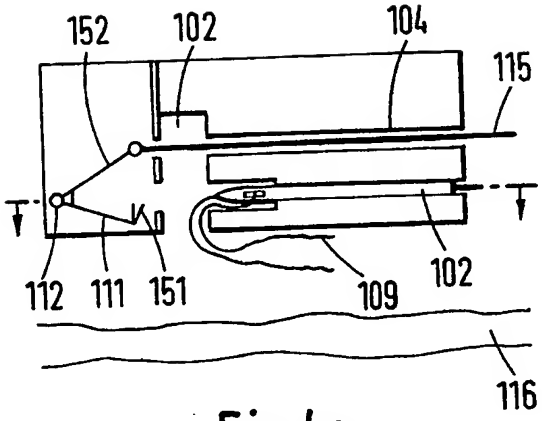


Fig.4a

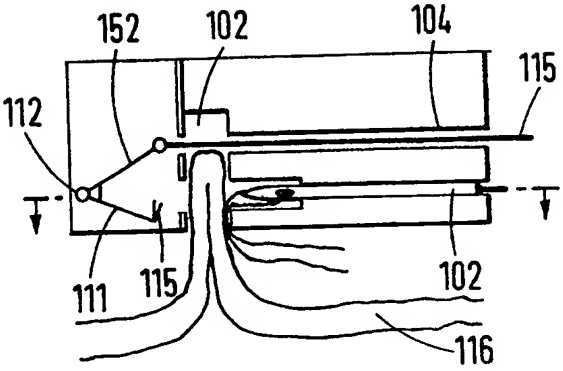
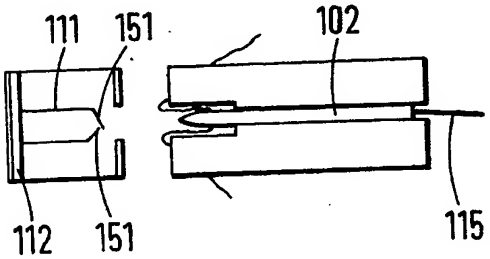
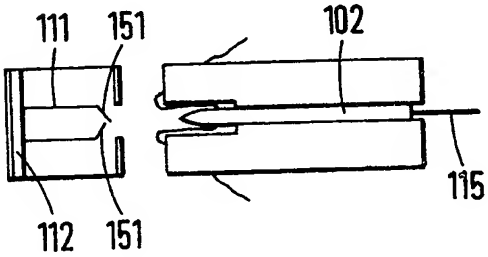


Fig.4b





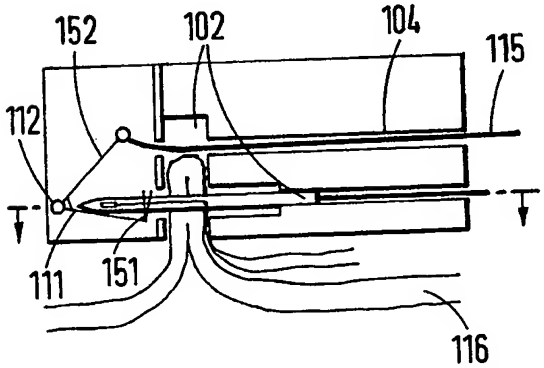


Fig.4c

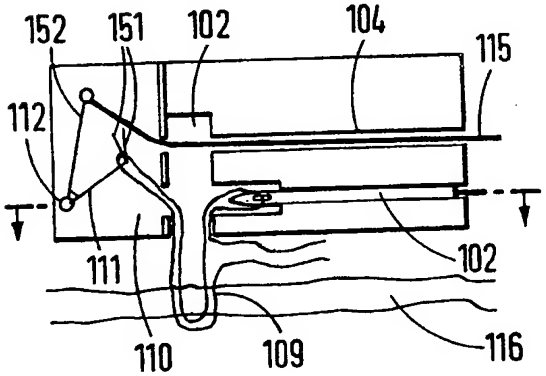
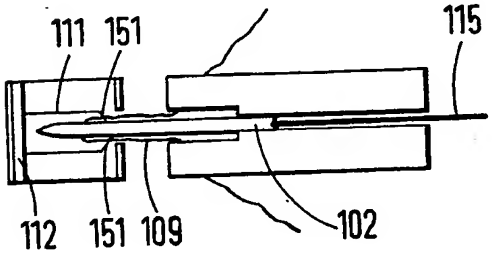
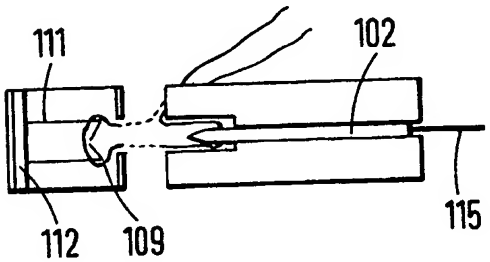


Fig.4d





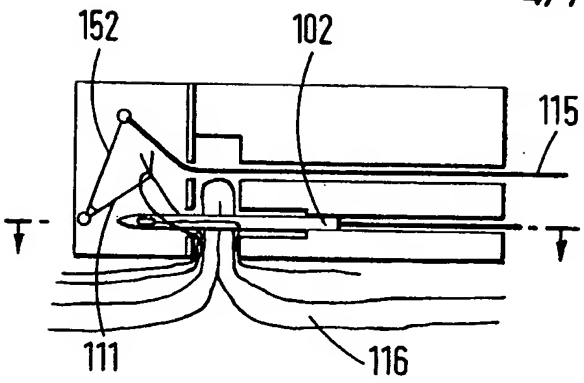


Fig.4e

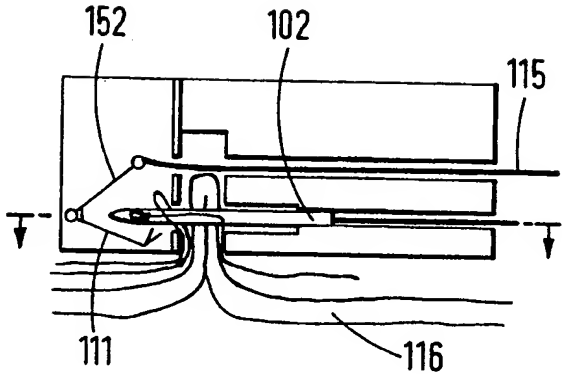
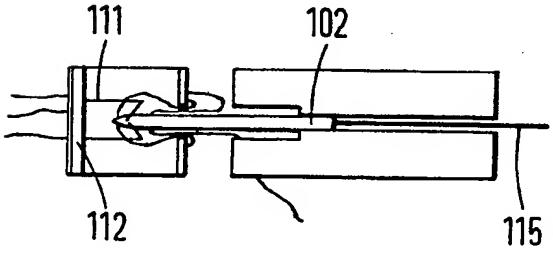
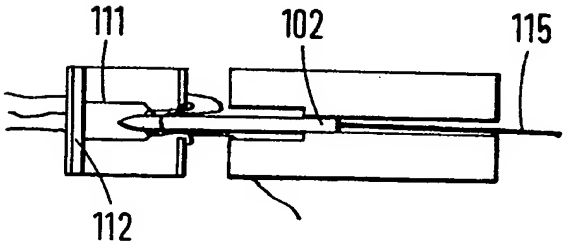


Fig.4f





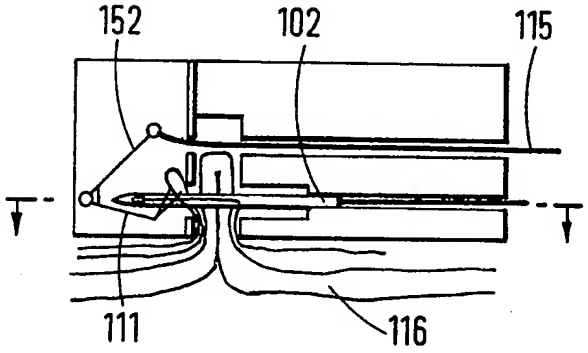


Fig.4g

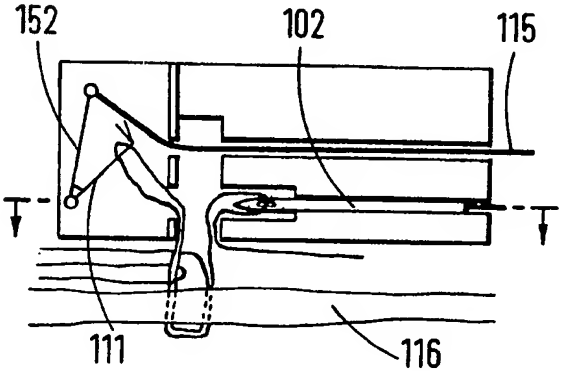
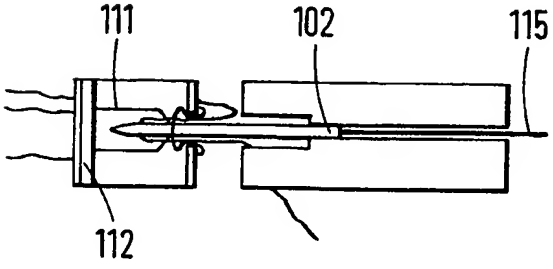
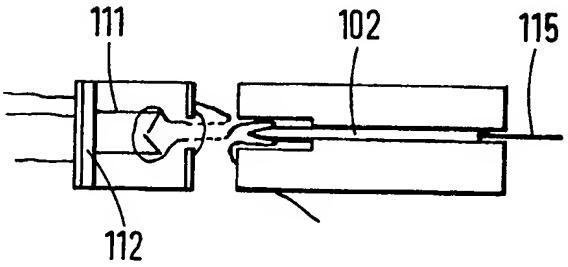


Fig.4h





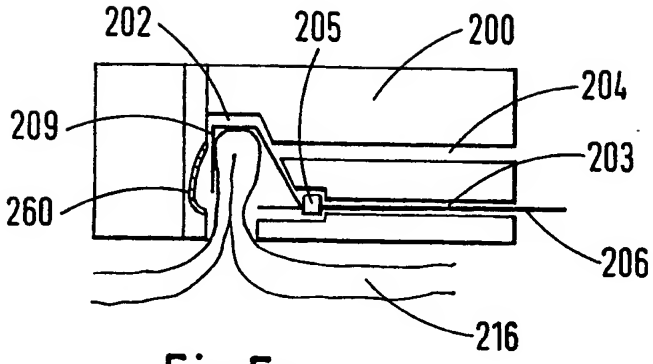


Fig.5a

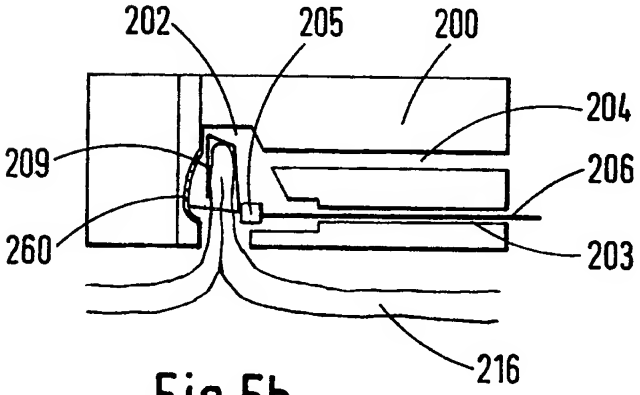


Fig.5b

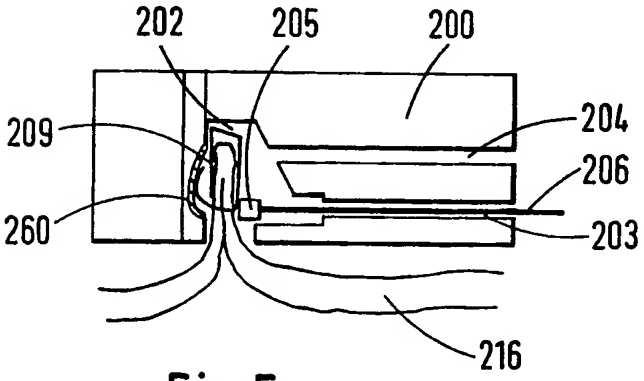


Fig.5c

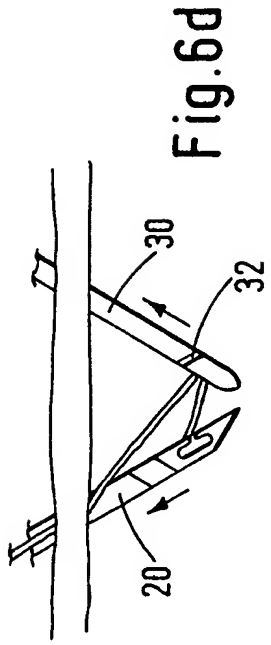


Fig.6d

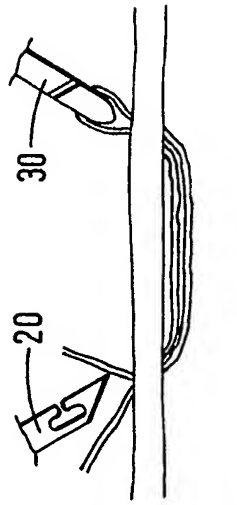


Fig.6e

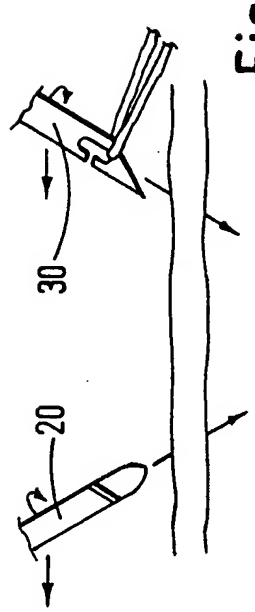


Fig.6f

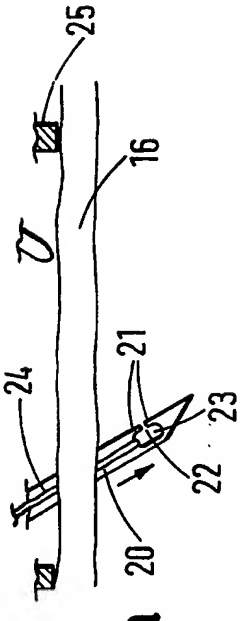


Fig.6a

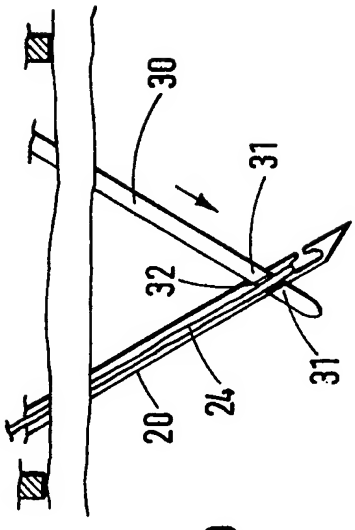


Fig.6b

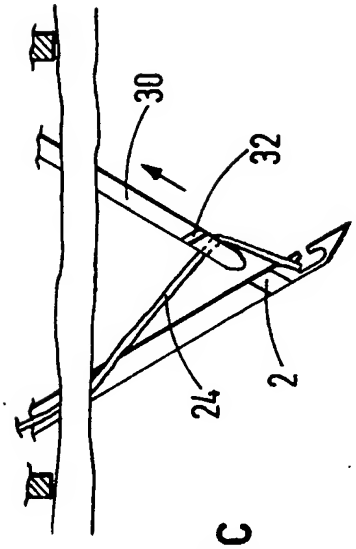


Fig.6c

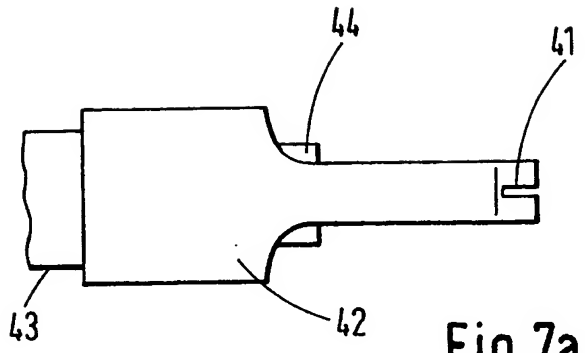


Fig.7a

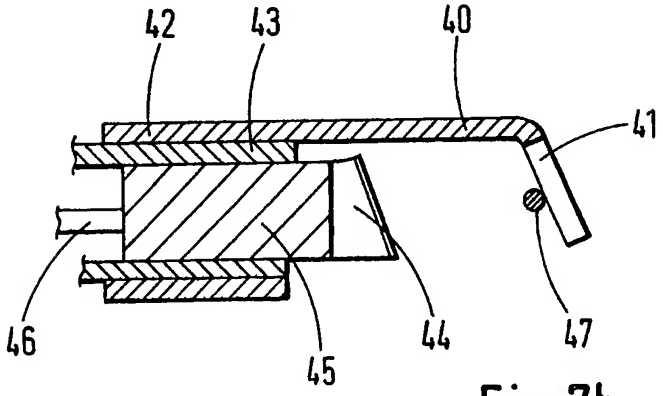


Fig.7b

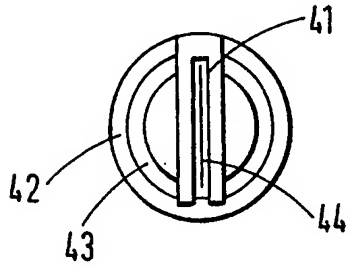


Fig.7c

SPECIFICATION

Sewing or stapling machine

This invention relates to sewing machines and stapling machines. The invention has particular application to sewing required in surgical procedures, and, more particularly, relates to sewing and stapling machines which can be used inside the body of a patient without the need to make an internal incision in the patient, the machine being controlled externally of the patient, for example by endoscopic means. For convenience such a machine is referred to below as an endoscopic sewing or stapling machine, and the ensuing description relates largely to endoscopic sewing and stapling machines. It is to be understood, however, that sewing and stapling machines according to the present invention could be used in other applications.

According to one aspect of the present invention there is provided a sewing machine for forming stitches in a substrate, comprising means for passing a thread into the substrate from one side thereof at a first location and for withdrawing the thread from the substrate at a second location spaced from the first location, the said means being remotely operable solely from the said one side of the substrate.

According to another aspect of the invention there is provided a stapling machine operating on similar principles. The machines according to the present invention open up the possibility of performing a wide range of internal surgical procedures without having to make an external incision in the patient. Potential medical uses of such machines could include the oversewing of bleeding or perforated ulcers, the oversewing of bleeding varices, the narrowing of lax internal anatomical sphincters or organs, the closure of internal holes or fistulae, the assistance in the removal of normal or abnormal tissue, and the attachment of materials or objects to the walls of tissue (for example for attaching gastric tubes for feeding purposes to the wall of the stomach, or for attaching X-ray opaque markers to mark the site of, say, a cancer, or for attaching a piece of material containing a drug to permit localised internal treatment).

Figures 1a, 1b, and *1c* show a first embodiment of a sewing machine according to the present invention, in three successive stages of operation;

Figure 2 shows, by way of example, one stitch pattern which can be formed by the machine of Figures 1*a* to 1*c*;

Figures 3a and *3b* are underplan and side elevational views respectively showing a second embodiment of a sewing machine;

Figures 4a to *4h* show diagrammatically the second embodiment of sewing machine in successive stages of operation, each Figure comprising two longitudinal sections through mutually perpendicular planes, in order to enable the operation of the machine to be more easily visualised in three dimensions, one of the longitudinal sections in each Figure being taken along the section line indicated in the other;

Figures 5a to *5c* show longitudinal sections through an embodiment of stapling machine according to the present invention, in successive stages of operation;

Figures 6a to *6f* show a third embodiment of the present invention in successive stages of operation; and

Figures 7a to *7c* are, respectively, a plan view, a vertical section and an end view of a thread guillotine for use in conjunction with the sewing machine of the present invention.

The embodiment shown in Figures 1*a* to 1*c* comprises a block 1 preferably formed of a transparent material such as perspex. A slot 2 is formed in the block 1, the slot extending from the front to the back of the block, i.e. in a direction perpendicular to the plane of the paper. The block also has two longitudinal channels 3 and 4 formed therein. The channel 3 receives a needle 5 which is longitudinally slidable in the channel 3 under the control of a control wire 6. The needle 6 has a head portion 7 in which is formed an eye 8, and a thread 9 to be used in sewing is passed through the eye 8. The channels 3 and 4 are continuous with corresponding channels 17 and 18 formed in a two-channel endoscope tube 19.

The block 1 also has a compartment 10 formed therein, distal to the slot 2. A shoe 11 is pivotally mounted in the compartment 10 about a pin 12. The rear portion 13 of the shoe 11 is resilient and serves to bias the shoe in an anti-clockwise direction into the position shown in Figure 1*a*. A hook 14 is mounted for pivotal movement on the pin 12. The hook 14 is approximately in the shape of a V, and a control wire 15, which passes down the channels 4 and 18, is attached to the hook 14 adjacent the vertex of the V. A source of suction (not shown) is connected to the proximal end of channel 18 for a purpose which will be described below.

Turning now to the operation of the machine, the initial position is shown in Figure 1*a*, with the machine positioned above a layer of tissue 16 in which it is desired to form stitches. Suction is then applied to the slot 2 to suck into the slot a double layer of tissue, as can be seen in Figure 1*b*. The depth of the slot 2 controls the amount of tissue which is sucked in. The needle 5 is then forced forwards through the double layer of tissue, as is also shown in Figure 1*b*. The needle carries with it the loop of thread 9. The tip of the needle strikes the shoe 11 which is thereby caused to pivot downwardly against the biassing force of the shoe portion 13. The control wire 15 is then pulled rightwardly to cause the hook 14 to pivot and thereby catch the loop of thread carried by the eye 8 of the needle 5. This can also be seen in Figure 1*b*. It should be mentioned at this point that the side of the head portion 7 of the needle has a groove (not shown) formed therein to allow the hook 14 to pass between the head portion 7 and the thread carried thereby.

As shown in Figure 1*c* the needle is then withdrawn leaving the loop of thread held between the

hook 14 and the shoe 11. The suction applied to the slot 2 is then released and the double layer of tissue leaves the slot. This is also shown in Figure 1*c*, from which it can be seen that the effect of the steps described above is to pass a loop of thread from one side of the tissue through the tissue at a first location and back out of the tissue on the same side at a second location from the first location. As will be appreciated, this has been done without requiring access to the opposite side of the tissue which one would expect to be inaccessible under normal circumstances.

The machine is then moved to the site of the next stitch, suction is re-applied and the needle passes through a double layer of tissue at a different point. It is possible to form a variety of different stitches using the machine, but one example is shown diagrammatically in Figure 2. This stitch pattern is formed by moving the machine between successive stitches in a direction perpendicular to the plane of the paper in the drawings of Figure 1*a* to 1*c*. Figure 2 is a view taken looking down on the upper surface of the tissue shown in Figures 1*a* to 1*c*, and it will be seen that each of the loops formed by the hook 14 and the shoe 11 passes through the preceding such loop. How this is achieved can be understood by imagining the effect of moving the needle forwardly from the position shown in Figure 1*c*, with suction re-applied to the slot 2 to suck the tissue into the slot. It will be appreciated that the forward end of the needle will pass through the loop of thread caught between the hook 14 and the shoe 11, carrying a new loop of thread with it. It should be mentioned that to assist this process a small groove can be formed in the upper surface of the shoe, up which the tip of the needle can slide. This enables the needle to pass under the loop of thread already caught between the hook and shoe, without the risk that the needle may simply push the existing loop further up the surface of the shoe. Once the needle has placed the second loop through the first loop the hook 14 is pivoted to allow the first loop to be cast off by pulling on the tail of the thread. The hook 14 is then pivoted downwardly again, so that when the needle is withdrawn the second loop of thread is caught thereby.

As already mentioned, the body 1 is preferably made of a transparent material, so as to make it easier for the operator to see, and hence control, the operation of the machine. The control mechanisms can pass down the channel of an existing endoscope, or the machine can be used independently with a small supervising endoscope passed in parallel with the control channel of the machine.

The embodiment shown in Figures 3*a* and 3*b* is modular in construction, and comprises modules A to G joined face to face and held in position by suitable means, for example, a pair of longitudinally extending bolts passing through aligned bores in the individual modules. In the embodiment illustrated the modules B and D are formed of a transparent material and the remaining modules are not, but others of the modules may be transparent, and indeed it is preferable for some purposes that at least the module A should be transparent.

The module A is the main body portion, and defines longitudinal channels 103 and 104, corresponding to the channels 3 and 4 shown in Figure 1. The channel 103 receives a needle 105, which is longitudinally slidable therein under the control of a control wire 106. The needle 106 has a head portion in which is formed an eye 108 and a thread to be used in sewing is passed through the eye. The channels 103 and 104 are continuous with corresponding channels 117 and 118 formed in a two-channel endoscope tube, the rest of the endoscope being omitted for simplicity in Figures 3*a* and 3*b*.

The module B has a slot 102 formed therein, which, as viewed in underplan view, extends across the central region of the module B and which, as viewed in elevation, extends from the top of the module to a location falling just short of the bottom.

The module B is separated by module C, which constitutes a spacer disc and which has an aperture 150 therein through which the needle 105 can pass, from the module D. Module D has a compartment 110 therein which is aligned with slot 102 in module B.

Modules E and F retain a pin 112 on which a U-shaped member 111 is pivotally mounted. The arms of the member 111 each carry a respective resilient wire 151. As can be seen in Figure 3, the wires converge towards one another at their tips as viewed in underplan, and, as can be seen in Figure 3*b*, the tip portions of the wires are bent upwardly and one of the wires is longer than the other and thus extends further upwards than does the other.

A control wire 115, which passes down the channels 118 and 104 is attached to an arm 152 which is, in turn, rigidly connected to the U-shaped member 111.

The module G provides a curved or bevelled front end to the device, so as to increase the ease with which it can be introduced into a patient.

A source of suction (not shown) is connected to the proximal end of the channel 118 for a purpose which will be described in more detail below and which is basically similar to that for which the source of suction is used in the embodiment of Figure 1.

The operation of the device of Figures 3*a* and 3*b* will now be described with reference to Figures 4*a* to 4*h*. It should be noted that these figures are diagrammatic in character. In each case module G has been omitted, and the modular construction of the remaining portion of the device has not been shown in detail.

The initial position is shown in Figure 4*a* with the machine positioned above a layer of tissue 116 in which it is desired to form stitches. Suction is then applied to the slot 102 via the channel 104 to suck into the slot a double layer of tissue, as can be seen in Figure 4*b*. The depth and width of the slot 102 controls the amount of tissue which is sucked in. The modular design of this embodiment makes it possible to vary the amount of tissue

sucked in, and hence vary the size of the stitches, simply by removing module B and replacing it by a module having a different thickness of depth of slot.

The needle 105 is then forced forwards through the double layer of tissue, as shown in Figure 4*c*. The needle carries with it a loop of a thread 109. The needle passes in front of the upwardly extending tip portions of both of the wires 151, as viewed in Figure 4*c*. The control wire 115 is then pushed leftwards, as shown in Figure 4*c*, to cause the U-shaped member 111 to pivot anti-clockwise and thus to cause the wires 151 to catch the loop of thread carried by the eye of the needle 105. The needle 105 is then withdrawn rightwards whilst the U-shaped member is rotated fully anti-clockwise carrying the thread upwards into the compartment 110. This is shown in Figure 4*d*. This last action forms the thread into a large diameter loop. This results from the fact that the wires 151 diverge from one another as considered in a direction running leftwardly from their tips.

The suction applied to the slot 102 is then released and the double layer of tissue, with the thread 109 passing through it, leaves the slot. This is also shown in Figure 4*d*.

The machine is then moved with respect to the tissue in any direction to the right of a plane drawn perpendicular to the plane of the paper and passing through the machine. Thus, the machine could be moved rightwardly in a direction parallel to its length, or at any angle less than 90° with respect to the aforesaid direction. The step shown in Figure 4*e* is then carried out, that is to say, suction is reapplied and the needle caused to pass through a double layer of tissue at a different point to that where the needle passed through the tissue in step 4*c*. As can be seen in Figure 4*e*, the forward end of the needle passes through the loop of thread already held by the U-shaped member 111, carrying a second loop of thread with it. Once the needle has placed this second loop through the first loop, the U-shaped member is pivoted clockwise, as shown in Figure 4*f*. The wires 151, being resilient, are forced apart by the needle and thus pass one on either side of the needle as the U-shaped member 111 travels to the position shown in Figure 4*f*, in which it is below the needle. In so doing the wires 151 drop the first loop onto the second loop.

The member 111 is then pivoted anti-clockwise, as shown in Figure 4*g*, so as to catch the second loop carried by the eye of the needle. This is shown in Figure 4*g*. Both wires 151 at this stage lie against the needle 102 and between the needle 102 and the adjacent portion of the thread 109.

As shown in Figure 4*h*, the needle 102 is then withdrawn rightwardly and the member 112 is pivoted further in an anti-clockwise direction, carrying the second loop upwards with it. As also shown in Figure 4*h*, the suction is then released to allow the tissue to leave the slot 102.

The above procedure is repeated as many times as are necessary in order to produce the desired number of stitches.

Various modifications may be made to the embodiments described above. One of these is that the machine can be provided with a plurality of slots 2 into each of which a double layer of tissue may be sucked. A single needle can then pass through each of these double layers of tissue, thus making a plurality of stitches in a single operation. Also, it should be understood that the stitch forming part of the machine could be modified to correspond to that of any one of a number of conventional sewing machines. For example, the stitching mechanism could be one which uses two threads, rather than one as in the illustrated embodiments.

As mentioned above, the module A is preferably transparent. This is to make it easier for the operator to see, and hence control the operation of the machine. Visibility may further be improved, both in the embodiment of Figures 3 and 4 and in the embodiment of Figure 1, by positioning a mirror in the slot 102 (or slot 2) at 45° to the longitudinal axis of the machine. By way of example this is shown diagrammatically as 153 in Figure 3b. This enables the user to see the double layer of tissue sucked into the slot 2. A still further improvement can be achieved by extending the endoscope optics right up to the slot 102 (or 2).

Some of the principles utilised in the above sewing machines can be applied with similar effect to the construction of a stapling machine which can also be used in a surgical environment. An embodiment of such a stapling machine is shown in figures 5*a* to 5*c*, which show successive steps in its operation.

The stapling machine comprises a body 200 which, if desired, may be of modular construction. The body is preferably wholly or partially of a transparent material. The body defines a cavity 202 into which tissue 126 may be sucked by suction applied through a suction channel 204. Before use, the cavity 202 is pre-loaded with a staple 209. The body also contains a second channel 203 through which extends a wire 206 carrying a piston 205 at its end. The cavity 202 has, in one wall thereof, an anvil plate 260, for a purpose which is described below.

In the starting condition shown in Figure 5*a*, the staple 209 comprises four consecutive rectilinear sections, namely a first upwardly extending section, a second horizontally extending section, a third diagonally downwardly extending section, and a fourth section, which is parallel to the second section, and has its free end directed towards the first section. In the condition shown in Figure 5*a* suction has been applied to the channel 204 to suck into it a double layer of tissue 216. As shown in Figure 5*b* the next step is for the piston 205 to be moved leftwardly by means of the wire 206, thus driving the fourth sections of the staple through the double layer of tissue so that its tip comes into contact with the anvil 260, and simultaneously deforming the remaining sections of the staple. As shown in Figure 5*c*, further leftward movement of the piston 206 causes the tip of the staple to ride along the anvil 206, thus twisting it around the first section of the staple and locking

the staple so that it exerts a compressive force of the tissue held by it. The illustrated embodiment shows only a single staple. However, the machine may carry a plurality of staples connected side by side as in the case of staples used, for example, in stationary applications. In this case, the row of staples is biassed, for example, by a spring exerting a force perpendicular to the plane of the paper as viewed in figure 5, a stop being provided to retain the row of staples in the correct position against the biassing force. Figures 6*a* to 6*f* show, in part, a further embodiment of a sewing machine according to the present invention. The construction of this embodiment will become apparent from the following description of how it operates. The machine comprises two needles 20 and 30. Before the stage shown in Figure 6*a*, the needles are withdrawn such that their tips are separated by about 5mm. Then, as shown in Figure 6*a*, the first needle 20 is passed obliquely through the tissue 16, as indicated by the arrow. The needle 20 has a pair of opposed barbs 21 separated by a slot 22. The slot 22 provides access to an opening 23. A loop of thread 24 is carried forwardly by the needle. The tissue 16 is held in place by suction applied to a tube 25, the distal end of which carries the sewing machine of which the needle 20 forms a part. Only the end of the tube 25 is visible in the figures. The proximal end of the needle 20 is guided for rectilinear movement in a bush (not shown).

As shown in Figure 6*b*, once the needle 20 has been passed through the tissue to the full extent which is required an identical needle 30 is inserted through the tissue at a location remote from that at which the needle 20 passed through the tissue. The needle 30 is angled oppositely to the needle 20 so that, as shown in Figure 6*b*, its path of travel intersects that of the needle 20. At this stage the needle 30 carries no thread. Furthermore, the needle 30 is rotated by 90° about its longitudinal axis compared to the needle 20. The needle 30 has a slot 32, corresponding to slot 22 of needle 20, and barbs 31, corresponding to barbs 21 of needle 20. As shown in Figure 6*b*, the needle 30 passes between the needle 20 and the loop of thread 24 carried by the needle 20. To assist in this the needle 20 is provided with a depression 26 which is obscured in Figure 6 but which can be seen in Figure 6*c*.

In the position illustrated in Figure 6*b*, the slot 32 is located immediately below the thread 24. This causes the thread 24 to pass through the slot 32 and thus causes it to be caught by the needle 30.

As shown in Figure 5*c*, the needle 30 is then partially withdrawn, and as it does so it pulls the loop of thread 24 with it. As shown in Figure 5*d*, when the needle 20 is then partially withdrawn the thread 24 is freed from the needle 20 and held only by the needle 30. Further withdrawal of both needles 20 and 30 to a position where both pass out of the tissue 16 causes the situation to be reached which is shown in Figure 6*e* where a stitch has been formed.

Each of the needles 20 and 30 is then rotated by 90° about its own axis, so that needle 20 assumes the orientation and function which was previously that of needle 30 and needle 30 assumes the orientation and function which was previously that of needle 20. The above described process is then repeated with the functions of the needles 20 and 30 interchanged. This procedure is continued as many times as are necessary to produce the required number of stitches.

The use of an endoscopic sewing machine according to the present invention gives rise to a requirement for a suitable means for securing knots and cutting thread. Secure knots are essential for surgery, and tying knots and cutting thread by remote control in confined spaces, as is necessary in conjunction with the use of the endoscopic sewing machines described above, imposes special requirements. Some ways of satisfying these requirements are therefore mentioned below.

One method of tying a knot is as follows. A washer having a central hole, the diameter of which is a clearance fit on the thread to be fastened is fed onto the thread. The thread is tied as a half-hitch around a pin pressed through the two walls of the end of a strong but flexible catheter tube. By holding the tail of the thread and pushing on the tube the half-hitch and washer in front of it may be run forward. When the desired position has been reached, the pin is removed remotely by pulling on a wire to which it is attached and which runs along the outside of the catheter. In another method of fastening the thread, a plastic washer is run over the thread down the endoscope channel. Plastic is preferred to metal because it is resistant to acid digestion. A compressible tapered sleeve is passed over the thread and a rammer bears down on the sleeve, distorting it tightly over the thread and against the washer while pull is exerted on the thread. Yet another method of fastening the thread uses a Z-shaped plastic strip having holes for the thread in the three limps of the Z-shape. There is a V-shaped slit cut in the proximal hole. The thread is run through all the three holes of the Z-shaped strip which is pushed through the endoscope channel. A pushing device compresses and folds the Z-shaped strip like a flattened concertina against the tissue. This tightens on the thread forcing it into the narrow V-shaped slit which holds the thread securely.

Figure 7 shows a thread guillotine for endoscopic use. This comprises a crooked leg 40 with a slit 41 cut centrally along its length at one end thereof. The leg 40 is formed on the end of a metal tube 42 which is pressed over the end of a small diameter plastic catheter tube 43. A knife blade 44 is held in a piston 45 which is free to move axially in the bore of the tube 43. A wire 46 attached to the piston 45 and running through the bore of the tube 43 controls the movement of the blade when pushed forward. The blade 44 passes through the slot 41 in the crooked leg, thereby acting as a guillotine to sever the thread 47.

Finally, mention may be made of a suction overtube to facilitate sewing down an endoscope by means of a machine according to the present invention, or indeed by some other means. The ov-

ertube envisaged is a transparent flexible tube which fits loosely over the endoscope. An air-tight seal is made with an elastic sleeve between the overtube and the endoscope. A hole of specific dimensions is cut in the extreme end or in the side of the overtube distally. Air is sucked from the overtube such that tissue to be sewed protrudes into the overtube where it is held in a conformation which enables the tissue to be readily transfixed by a threaded needle.

It is to be understood that the various devices described above as being ancillary to the sewing machine according to the present invention are believed to be novel in their own right and form independent aspects of the present invention.

CLAIMS

1. A sewing machine for forming stitches in a substrate, comprising thread-carrying means for passing a thread into the substrate from one side thereof at a first location and for withdrawing the thread from the substrate at a second location spaced from the first location, the said means being remotely operable solely from the said one side of the substrate.

2. A machine according to claim 1, comprising means defining a slot open towards the substrate, and means for drawing a double layer of the substrate into the slot, the thread-carrying means being disposed for movement from a retracted position to an extended position, in which movement it carries a loop of the thread into and through the said double layer, and further comprising means for catching the said loop after it has been passed through the double layer of substrate and holding the said loop while the thread-carrying means is withdrawn to the retracted position.

3. A machine according to claim 2, wherein the catching means is movable from a catching position to a position in which the loop caught thereby is positioned so that subsequent movement of the thread-carrying means from said retracted position to said extended position carries a further loop of thread through the previously caught loop.

4. A machine according to claim 2 or 3, comprising a channel communicating with said slot for supplying suction thereto to effect the said drawing in of the double layer.

5. A machine according to claim 4, comprising a block having distal and proximal ends, the block defining a compartment adjacent the distal end housing the catching means, said slot being defined in the block on the proximal side of the compartment, said suction-supplying channel being defined in the block on the proximal side of the slot, a further channel being defined on the proximal side of the slot and communicating with the slot, said thread-carrying means being slidably received therein for movement between said retracted position, in which the thread-carrying means is substantially wholly within said further channel, and said extended position, in which the thread-carrying means extend across said slot into said compartment.

6. A machine according to claim 5, wherein control means for controlling the catching means extends through the suction-supplying channel and across said slot into said compartment to connect with the catching means.

7. A machine according to claim 6, wherein said control means comprises a flexible wire, and wherein the machine further comprises a further flexible wire for moving the thread-carrying means between the retracted and extended positions.

8. A machine according to claim 6 or 7, wherein the catching means comprises a shoe resiliently mounted in the compartment for pivotal movement about an axis transverse to the length of the block, and a hook pivotally mounted at one end of the shoe and movable by said control means between a position in which the other end thereof is in contact with the shoe and a position in which there is no such contact.

9. A machine according to claim 6 or 7, wherein the catching means comprises a pair of arms defining a U, the U-shaped member being mounted in the compartment for pivotal movement about an axis transverse to the length of the block and a pair of resilient members each extending from a respective one of said arms, the resilient members converging towards one another adjacent the outward ends thereof, the U-shaped member being movable by said control means between an outward position in which, when the thread-carrying means is in its extended positon both resilient members are closely adjacent the thread-carrying means on the same side thereof, and an inward position in which the resilient members are located inwardly of the thread-carrying means.

10. A machine according to any of claims 5 to 9, wherein the block is formed of a plurality of disconnectible modules located face to face, one of said modules being a module defining said slot.

11. A machine according to any of claims 5 to 10, wherein proximally of the slot the block is transparent.

12. A machine according to any of claims 5 to 11, further comprising mirror located in the said slot and angled with respect to a line extending between the proximal and distal ends of the block.

13. A machine according to claim 1, comprising means for holding said substrate, first and second needles guided for movement along the axis thereof and arranged so that said axes intersect at a point located away from said substrate on the opposite side thereof to said one side thereof, means on each needle for holding a loop of thread and for catching the loop of thread held by the other needle.

14. A machine according to claim 13, wherein the thread-holding and thread-catching means comprises an opening formed in the needle and a slot communicating with said opening and providing access thereto.

15. A machine according to claim 14, wherein each needle is rotatable about the axis thereof between a thread-transporting position and a thread-releasing position at 90° thereto in which the other needle can remove the thread transported therto.

16. A machine according to any preceding claim, mounted on an end of an endoscope.

17. A stapling machine for inserting a staple in a substrate, comprising means defining a slot open towards the substrate, the slot being configured to receive at least one staple having opposite end portions which are spaced from one another to define a gap therebetween, means for drawing a double layer of the substrate into the slot and through said gap, and means for forcing one of said staple end portions through the double layer of substrate.

18. A machine according to claim 17, comprising an anvil disposed in the slot adjacent the other of said staple end portions and arranged so that when said one staple end portion is driven through the double layer of substrate it strikes the anvil and is deformed thereby into a position closely adjacent said other staple end portion.

19. A machine according to claim 17 or 18, comprising a channel communicating with said slot for supplying suction thereto to effect said drawing in of the double layer.

20. A machine according to any of claims 17 to 19, mounted on an end of an endoscope.

21. A guillotine for use in severing a thread, comprising a tube, a leg extending from one end of the tube and having an inwardly directed end portion with longitudinal slot formed therein, and a blade mounted on mounting means which are arranged to move longitudinally within the tube between a forward portion in which the blade passes through said longitudinal slot and rearward position in which the blade is spaced from the longitudinal slot.

22. A guillotine according to claim 21, comprising a catheter tube, the said mounting means being arranged to slide within the catheter tube and the tube which has the said leg being fixedly mounted on the exterior of the catheter tube.

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(54) IMPROVEMENTS IN OR RELATING TO FORCEPS INSTRUMENTS

(71) We, RICHARD WOLF GmbH, a German Body Corporate, of Pforzheimer Strasse 22, D-7134-Knittlingen, Germany,

do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement: —

The present invention relates to forceps instruments for fitting tantalum clips for sealing off the Fallopian tubes in the human female, the instrument comprising a barrel with an operating handle at its proximal end to close and open forceps for the clips at the distal end of the barrel while observation takes place by means of an optical system.

To seal off the Fallopian tubes for contraceptive purposes, clips made of tantalum are fitted, using a special forceps instrument, while observation takes place visually. Two forceps units are used for this, namely the forceps proper for fitting the clips (hereinafter referred to as the clip forceps), and a smaller pair of forceps or movable hook to allow the Fallopian tube to be brought within the reach of the actual clip-forceps and to allow it to be taken hold of more satisfactorily. In such known devices the optical system is housed in a special tube alongside the clip-forceps. This is a disadvantage both because the immediate area of operations cannot then be seen even though the optical system looks out on it at along a 160° line of sight, and also because it increases the diameter of the device.

It is an object of the invention firstly to keep the diameter of the forceps instrument and its optical system as small as possible, and secondly to arrange the optical system in such a way that the area between the jaws which is the area of operations can be observed directly.

The invention accordingly consists in a forceps instrument for fitting tantalum clips to seal off a Fallopian tube in the human female, comprising a barrel having at its distal end forceps jaws for holding a tantulum clip, an operating handle at the proximal end of the barrel, for moving the barrel axially with respect to the jaws to close and open the jaws, and an optical system for observing the fitting of a tantalum clip on a Fallopian tube during the closing of the jaws, including a viewing tube passing centrally through the barrel and terminating at the distal end of the barrel between the forceps jaws.

This construction gives a shape of smaller cross-section in comparison with known clip-forceps, which is important from the patient's point of view, and allows the area of operations to be observed directly.

In order that the invention may be more clearly understood, reference will now be made to the accompanying drawings which show one embodiment thereof by way of example, and in which: —

Fig. 1 shows a side-view of a clip-forceps instrument according to the invention,

Fig. 2 shows an interrupted longitudinal cross-section through the instrument of Fig. 1,

Fig. 3 shows an enlarged cross-section along line A-B of Fig. 2, and

Fig. 4 shows an enlarged cross-section along line C-D of Fig. 2.

Referring now to the drawings, the clip-forceps instrument shown consists of a tubular barrel 1, a guide sleeve 2 for the barrel, a pair of forceps jaws 3, 4, an operating handle in the form of a scissors-grip 5 and an internal viewing tube comprising tubular members 6 and 7 which are rigidly secured together adjacent the distal end of the barrel as by soldering for example. At the proximal end of the barrel a collar 9 on a turned part 8 having a tapered recess (not shown) for receiving an eyepiece 26 of

the optical system projects into the sleeve 2 and between the collar 9 and the tubular member 6 is mounted a spacer bush 10. Grub-screws 11 and 12 clamp parts 2, 6, 8, 9 and 10 together into a unit.

The tubular member 7 has, towards its distal end, two longitudinally orientated grooves 13 in which are mounted the limbs 3*a* and 4*a* of the two jaws 3 and 4 of the forceps. A spring locking-ring 14 is firmly engaged in suitable square-cornered annular grooves in the tubular member 7 and in the limbs 3*a*, 4*a* of the two jaws. To allow it to be inserted in the annular grooves this ring is a split ring and it is secured rigidly to the tubular member 7 by means of two small rivets located at 15.

The position of the limbs 3*a*, 4*a* of the jaws 3, 4 in the barrel 1 enables the jaws to be biassed into a normally open position by the action of a spring to be described. To provide a seal within the instrument against gas, e.g. carbon dioxide, escaping from the abdominal cavity, sealing-rings 16, 17 are fitted into appropriate annular grooves in the member 7 and bush 10 respectively.

The scissors-grip 5 consists of a pair of handle parts 18 and 19 which are connected together by a pivot-screw 20. A leaf-spring 21, which is fixed at one end to handle 18 by a knurled screw and which at the other end has a hinged, that is to say articulated, connection to an ear 22 on handle part 19, holds the forceps jaws normally in the open position. Handle part 18 of the grip of the forceps is securely connected to the sleeve 2 by soldering.

As will be apparent from Figure 4 particularly, the inner end of the handle part 19 projects into an axial slot 24 in the sleeve 2, formed for example by milling, and has a square cut-out accommodating a projection 23*a* of an axially movable fork-shaped pusher member 23, the projection being securely soldered to the handle part 19 in the cut-out. A U-shaped part of the pusher member 23 projects into a slot in the barrel inside the sleeve 2 and engages the sides of the slot 24 which guides the pusher member with respect to the sleeve and limits the axial movement of the pusher member, the slots in the barrel and sleeve permitting the pusher member to slide therein when the handle part 19 is moved. The internal recess in the U-shaped part of the pusher member is such as to receive the tubular member 6. By moving the handle part 19 towards or away from the handle part 18 the barrel 1 is moved axially in the sleeve to move the jaws via the pusher member 23. Because of the engagement of the pusher member in the slot 24 it is impossible for the axially-movable assembly in the forceps instrument (handle 19, pusher member 23 and barrel 1) to turn with respect to the sleeve 2.

There is no necessity for the scissors-grip 5 and the pair of jaws 3, 4 forming the mouth parts of the forceps to lie in the same plane in the way shown in the drawing. It may even be advantageous for the operating handle to lie in a plane which is at an angle of from 30 to 45° with respect to the plane of the mouth of the jaws since when looking through the optical system the operator may use the instrument with the scissors grip held in the uppermost position and can thus manage better if the operating handle is offset.

The proximal end (not shown) of the optical system 25 (which has the eye-piece 26) and a laterally arranged connection 27 which projects at right angles or is directed obliquely backwards and which allows a light-conducting cable to be connected), is tapered for engagement in the tapered recess of the part 8 and is secured to the instrument by means of a union nut 28 and a screw 29. A suitable form of locking is provided so that the light connection 27 will be in the right place, i.e. so that the light-conducting cable leading to the light source will get in the doctor's way as little as possible.

For accurate lining-up, of the parts 2, 6, 8, 9 and 10 during assembly of the instrument, the spacer bush 10 has a circumferential V-groove 30 in which fixing screw 11 engages. This adjustment can also be used to move the pair of jaws 3, 4 described above to the appropriate position relative to the handle 5.

The optical system 25 has a 180° line of sight so that it can see straight into the area of operations, that is to say between the jaws 3, 4. It is set slightly back in the tubular member 7 at the distal end so as not to be damaged.

The method of operation is as follows: a tantalum clip 31 is fitted between the two open jaws 3, 4. The forcep instrument and with it the optical system are then inserted in the abdominal cavity, and the Fallopian tube surrounded under visual observation. The doctor takes hold of handle 19 and moves it towards handle 18 in opposition to spring 21. When this is done the barrel 1 moves in the distal direction in relation to the optical system, slides over the jaws 3, 4 forming the mouth and as it does so closes the pair of jaws and thus the clip 31. The Fallopian tube is sealed off and passage through it blocked. If the doctor now releases his pressure on grip 19, spring 21 will propel it to its original position and at the same time barrel 1 will slide back and the jaws 3, 4 of the forceps will open again as a result of the spring action.

WHAT WE CLAIM IS:—

1. A forceps instrument for fitting tantalum clips to seal off a Fallopian tube in the human female, comprising a barrel having at its distal end forceps jaws for holding a tantalum clip, an operating handle at the proximal end of the barrel, for moving the barrel axially with respect to the jaws to close and open the jaws, and an optical system for observing the fitting of a tantalum clip on a Fallopian tube during the closing of the jaws, including a viewing tube passing centrally through the barrel and terminating at the distal end of the barrel between the forceps jaws.

2. An instrument as claimed in claim 1, wherein the viewing tube includes two tubular members of which one member having diametrically opposed axial grooves therein is mounted in the distal end of the barrel and is rigidly connected to the distal end of the other tubular member which extends beyond the proximal end of the barrel and wherein the jaws which project from the distal end of the barrel have mounting limbs which engage in said grooves respectively and are immovable axially of the viewing tube.

3. An instrument as claimed in claim 2, wherein the limbs of the forceps jaws are connected to said one tubular member, in said barrel by a split spring ring to prevent axial movement of said limbs relative to the viewing tube.

4. An instrument as claimed in claim 1, 2 or 3, wherein the operating handle comprises a scissors-grip having two handle parts of which one handle part is rigidly connected at the proximal end of the instrument to a guide sleeve surrounding the proximal end of the barrel and rigidly connected to the viewing tube, and the other handle part which is spring-urged away from said one handle part extends into an axial slot in said sleeve and is rigidly connected to the barrel by a fork shaped member receiving the viewing tube, whereby the barrel can be moved axially to close and open the forceps jaws by closing and opening the handle parts.

5. An instrument as claimed in any preceding claim, wherein the operating handle lies in a plane which is at an angle of from 30 to 45° with respect to the plane of the mouth of the forceps jaws.

6. A forceps instrument substantially as hereinbefore described with reference to the accompanying drawings.

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1 452 185 COMPLETE SPECIFICATION
1 SHEET

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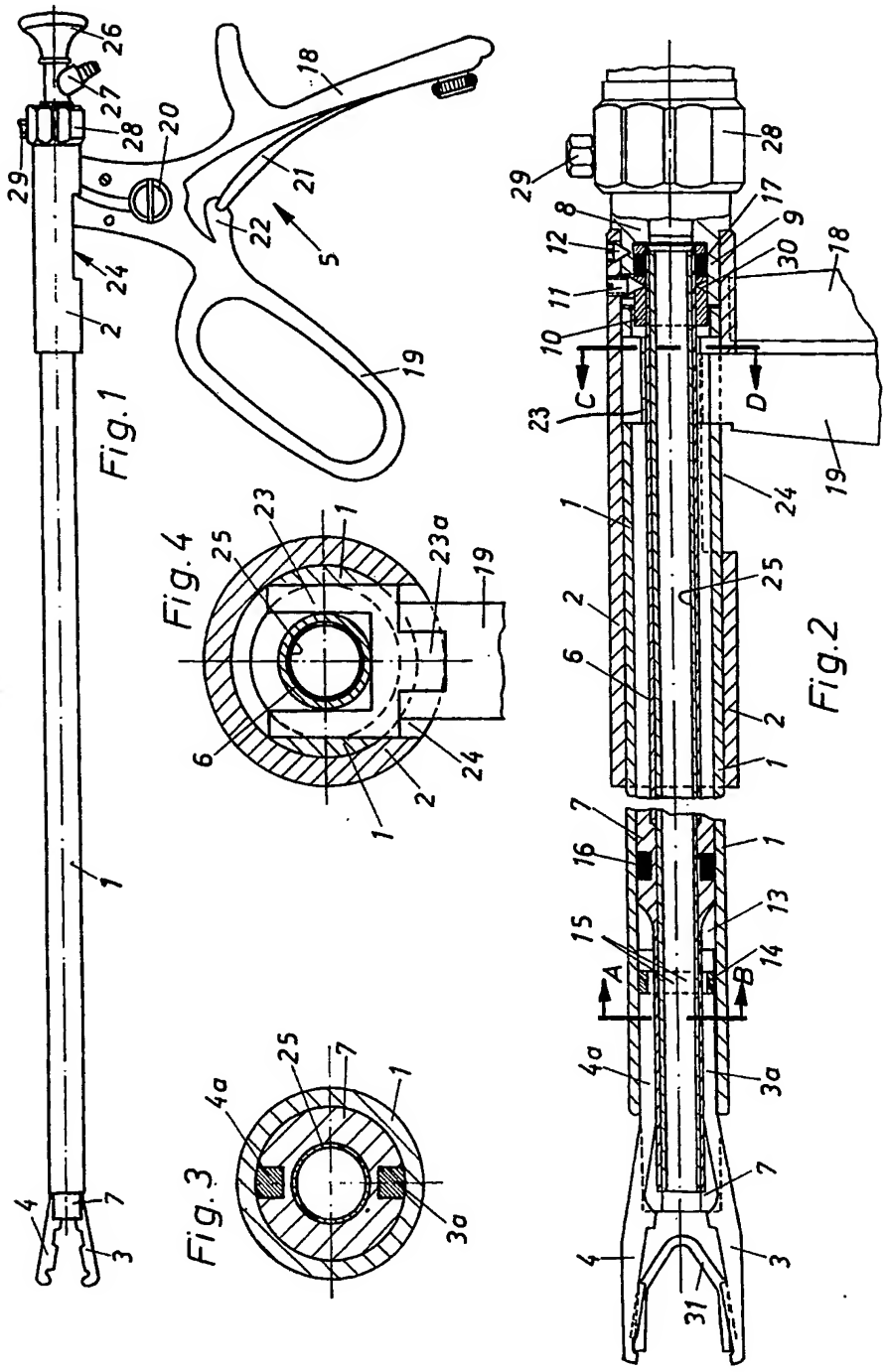

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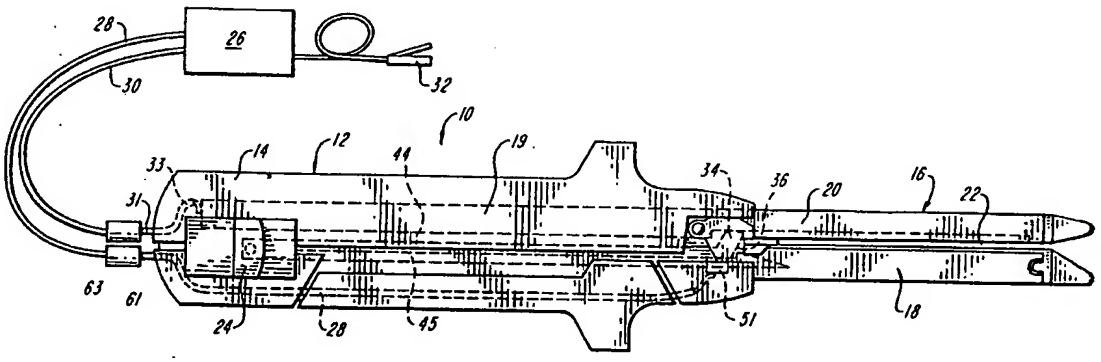

(57) Abstract

An electrosurgical tool (10) comprises a retractable cutting blade (34) movable along a linear cutting path and an electrical energy supply source (26) which communicates electrical energy (e.g. radio frequency energy) through the cutting blade (34) and to tissue adjacent the cutting blade. During surgical procedures the electrosurgical cutting device (10) is able to simultaneously cut tissue and cauterize, or fuse, the tissue in areas adjacent the incision through the application of electrical energy. The effect is a reduced amount of bleeding associated with surgical procedures and an enhanced ability to control and eliminate bleeding. Optionally, the electrosurgical cutting device (10) may also include a supply of surgical staples (38) which are deployed simultaneously with the cutting action and delivery of electrosurgical energy to adjacent tissue.

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ELECTROSURGICAL CUTTING TOOL

Background of the Invention

The present invention relates to an electrosurgical tool which is adapted to simultaneously cut, fuse, and cauterize the cut tissue so as to improve hemostasis.

Surgical procedures often require incisions to be made in internal organs, such as the intestine, causing profuse bleeding at the site of the incision. Prompt control or elimination of the bleeding is of paramount importance to the success and safety of the procedure.

Currently known surgical cutting devices utilize different techniques to control or eliminate bleeding. One known device is the Proximate Linear Cutter available from the Ethicon, Inc. of Sommerville, New Jersey. This device is specifically adapted to make an incision in tissue or an organ such as the intestine. The device engages a portion of the tissue or organ between two tyne-like members. To effect cutting, a blade mounted on one of the tynes travels along a predetermined path, thereby making a linear incision through the tissue or organ. Simultaneously, surgical staples are deployed by the cutting device on either side of the incision, resulting in the separation of the organ

into two segments, each of which is sealed adjacent to the incision by surgical staples. Despite the use of surgical staples and the precise cutting of the tissue, bleeding is not entirely eliminated and separate cauterization procedures must often be utilized to control or stop bleeding.

Surgical devices also are known which utilize electrical current in the form of radio frequency (RF) energy to cauterize tissue and to prevent or control bleeding. U.S. Patent No. 4,651,734 discloses a surgical scalpel modified to include an electrode. This scalpel has the ability to cut tissue and, when properly positioned, to cauterize tissue following a cutting procedure. Such a surgical tool is useful but does not simultaneously cut and cauterize tissue. The separate cauterization procedure which must be utilized is relatively time consuming and may result in unnecessary bleeding. Moreover, such a scalpel is not well suited to many surgical procedures such as the transection of the intestine.

Accordingly, there is a need for a surgical tool which conveniently and safely enables precise incisions to be made in internal organs, and which simultaneously is able to eliminate essentially all bleeding which results from the incision.

It is thus an object of the invention to provide a surgical tool which has improved cutting capability and which decreases some of the risk associated with surgery by minimizing the amount of

bleeding resulting from incisions. Another object is to provide a surgical tool which is adapted to simultaneously cut tissue and to cauterize the cut tissue. A further object is to provide an electrosurgical tool which is specifically adapted to make linear incisions in internal organs and, simultaneously, to fuse the tissue adjacent to the incision in order to eliminate any associated bleeding. Other objects of the invention will be apparent upon reading the disclosure which follows.

Summary of the Invention

The present invention comprises an electrosurgical cutting tool which is able to effect a precise incision through tissue, while at the same time ensuring that essentially all of the bleeding which results from the incision is controlled or eliminated. The electrosurgical cutting tool features a housing which includes a handle portion and a cutting template element which is disposed adjacent to the handle portion of the housing. The cutting template preferably includes first and second elongate tyne elements which define a tissue engaging space. A first tyne element includes a retractable cutting blade which is adapted to travel along a linear cutting path defined within the first tyne. The cutting blade is electrically insulated from the remainder of the tool and is in electrical communication with an active electrode which provides a source of electrosurgical energy to the blade. The surgical cutting tool of the invention also includes a mechanism, preferably located on the handle, which controls the movement of the blade along the cutting path.

The electrosurgical cutting tool may be a bipolar device or a monopolar device. In the preferred bipolar configuration an active electrode supplies electrical current to the blade, and a return electrode is disposed on a tissue-contacting portion of the second tyne. A return electrode is not integrally associated with the tool when it is configured as a monopolar device. Instead, a ground plate, remote from the tool itself, is positioned to contact a portion of the patient's body.

The electrosurgical energy provided to the cutting blade, preferably in the form of radio frequency energy, improves the mechanical cutting ability of the blade, and more importantly, facilitates cauterization and/or fusion of the tissue following the incision. It has been found that the use of radio frequency energy in connection with the cutting tool effectively allows the simultaneous cutting of tissue, and cauterizing and fusing of tissue adjacent the incision in order to eliminate virtually all resulting bleeding.

In another embodiment of the invention a plurality of surgical staples may be deployed by the device during a cutting procedure. In this embodiment a surgical staple cartridge is disposed within the first tyne, defining a central longitudinal groove through which the cutting blade is able to travel. The surgical staple cartridge includes a plurality of staples, preferably disposed in dual rows on either side of the longitudinal groove. Upon movement of the blade, a staple

ejecting device travels with the blade along the length of the staple cartridge causing the staples to be deployed through the tissue. A staple closing mandrel preferably is disposed in the second tyne to effect closure of the staples. This embodiment is advantageous as it allows the tissue to be cut, and at the same time, enables a row of staples to be deployed adjacent the incision while electrical current is passed through the blade to eliminate bleeding by effecting cauterization and tissue fusion. In some instances it may be desirable to deliver electrosurgical energy through the surgical staples as well as through the blade.

Brief Description of the Drawings

Figure 1 schematically illustrates the surgical cutting tool of the invention, including a supply source of electrosurgical energy.

Figure 2 is an exploded side view of the electrosurgical cutting tool illustrated in Figure 1.

Figure 3 is a sectional view of the electrosurgical tool of Figure 2 at lines A-A.

Figure 4 is a sectional view of the electrosurgical tool of Figure 2, at lines B-B.

Figure 5 is a sectional view of the electrosurgical tool of Figure 2 at lines B-B in an embodiment which does not include a surgical staple cartridge.

Detailed Description of the Invention

Figures 1 and 2 illustrate one embodiment of the invention in which the surgical cutting tool 10 comprises a housing 12 including a handle portion 14. Adjacent handle portion 14 is cutting template element 16 which includes a first tyne 18 and a second tyne 20. The two tynes 18, 20 of cutting template element 16 are substantially parallel and define a tissue engaging space 22 into which is inserted the tissue or organ to be incised. In a preferred embodiment, the surgical tool 10 includes a lever 24 which facilitates the movement of a cutting blade 34 along a predetermined path.

Figure 1 further illustrates an electrosurgical generator 26 which serves as an energy source from which electrical current, preferably in the radio frequency range, is communicated to the cutting tool through insulated wire 28. Insulated wire 30 communicates through connector 31 and internal ground wire 33 with a conductive portion of tyne 20 which serves as a ground. A control switch 32, preferably in the form of a foot petal, may be used to control the power supplied to the cutting tool. Alternatively, a control switch may be disposed on a portion of the cutting tool such as the housing 12.

As best shown in Figures 1 and 3, blade 34 can be retracted when not in use. In the retracted position blade 34 is disposed rearward of the first tyne 18 within a forward portion of housing 12.

Blade 34 includes a cutting edge 36 disposed at the leading edge of the blade. Further, a blade actuation arm 44 which extends into housing 12 is either attached to or integral with blade 34. The blade 34 is adapted to move along the longitudinal axis x of the tyne 18 upon actuation of lever 24 in order to effect the cutting of tissue.

A surgical staple cartridge 38 may optionally be seated within the first tyne 18, as illustrated in Figures 1 through 3. Cartridge 38 is adapted to securely fit within a channel 39 formed in tyne 18. The staple cartridge 38 includes a central cutting groove 40 through which the cutting blade 34 passes during a cutting procedure. Dual rows of openings 42 through which surgical staples (not shown) emerge straddle either side of groove 40.

As further illustrated in Figures 1 and 3, lever 24 preferably is connected to the blade 34 through an actuation arm 44. Forward movement of lever 24 thus effects movement of the blade 34 causing it to traverse the cutting groove 40. Preferably, a staple ejecting mechanism, such as ejection arms 45, is actuated simultaneous with actuation of the blade. In this way staples are ejected through openings 42 as the blade traverses the groove 40. As shown in the illustrated embodiment lever 24 may be connected to ejection arms 45 such that movement of the lever 24 also controls movement of the ejection arms 45.

Figure 5 illustrates an embodiment of the invention in which the electrosurgical cutting tool does not utilize surgical staples. In this embodiment the tissue contacting surface 41 of tyne 18 is constructed of or coated with a non-conducting material, such as a suitable polymer. Surface 41 defines a cutting groove 43 through which blade 34 travels when it effects a cutting procedure.

As shown in Figure 4, tyne 20 is secured within housing segment 12a which preferably is detachable from housing segment 12b associated with tyne 18. Further, tyne 20 has a tissue-contacting surface 48 which faces first tyne 18. A central groove 52 is formed in surface 48, superimposable with cutting grooves 40 or 43 of tyne 18, to facilitate movement of the blade along longitudinal axis x.

In an embodiment in which surgical staples are to be deployed simultaneously with a cutting procedure, staple cartridge 38 is present within tyne 18. In addition, surface 48 of tyne 20 includes a mandrel with a plurality staple-closing depressions 50 which correspond to the openings 42 in staple cartridge 38. Preferably, dual rows of depressions are disposed on either side of groove 52. In an embodiment in which a staple cartridge is not utilized, the surface 48 may be substantially smooth and absent depressions 50. In either embodiment, however, surface 48 of tyne 20 should be made of a conductive material so that it may serve as a return electrode for electrical energy delivered through the cutting blade.

In some instances, it may be desirable to apply electrosurgical energy through the surgical staples as well as through blade 34. One skilled in the art could easily modify the electrosurgical surgical tool described herein by connecting internal wire 28 to the staple ejection arms 45 as well as to the blade 34.

Figures 1 through 5 illustrate the connection of the cutting tool 10 to electrosurgical generator 26. As illustrated, an inner wire 28 extends between conductive bushing 51 and electrical connector 61 which protrudes from housing 12. Insulated wire 28 may be attached to electrical connector 61 through connector 63. Bushing 51 communicates electrical current from the generator 26 to blade 34, directly or through blade actuation arm 44. In a preferred embodiment arm 44 and blade 34 are able to slide within bushing 51 while maintaining electrical contact therewith.

In a preferred embodiment, the electrosurgical cutting tool 10 of the invention comprises a bipolar cutting tool in which the cutting blade 34 is electrically isolated from the remainder of the tool and serves as an electrode to deliver electrosurgical energy to the tissue. In this embodiment tyne 20 serves as the return or ground electrode. In other embodiments, it is possible that the surgical tool may comprise a monopolar tool in which electrosurgical energy is delivered through the cutting blade 34, and a separate ground plate (not shown) serves as the return electrode.

In the preferred bipolar mode surface 48 of tyne 20 serves as a ground electrode. Accordingly, exterior ground wire 30 communicates with internal ground wire 33 through connector 31. Internal ground wire 33, in turn, is in electrical communication with a conductive internal anchoring component 19 of tyne 20. Where the cutting device is used in the monopolar mode, external ground wire 30 should not communicate with tyne 20, and the tissue contacting surface 48 of tyne 20 should be made from or coated with a non-conductive material.

As noted above, generator 26 supplies electrosurgical energy to the cutting blade. Virtually any generator which provides electrosurgical energy for medical applications may be used with the present invention. Preferably, the generator is a voltage determinative, low source impedance generator which provides radio frequency energy. Preferably, a suitable generator can supply up to 2 amps of current and has an impedance value of less than 10 ohms.

The energy supplied by generator 26 to the electrosurgical cutting device is preferably in the radio frequency range. Although virtually any frequency in the RF range may be supplied to the cutting device, the preferred frequency range is about 500 to 700 KHz, and most preferably about 550 KHz.

The energy requirements of the electrosurgical tool of the present invention are dynamic and depend to a great extent upon the impedance values of the tissue encountered by the blade during cutting procedures. The impedance of tissue varies among tissue types and the amount of blood present in or around the tissue. The amount of current delivered by the tool to the tissue is a function of the impedance of the tissue. Where tissue contacted has a lower impedance value, more current will be delivered to the tissue by the blade, and, conversely, less current will be delivered to tissue having a higher impedance value. Generally, the amount of current delivered to tissue ranges between about 0.5 and 2.0 amps. The voltage applied to the tissue between the blade and the return electrode typically is between about 50 to 100 volts rms.

The surgical tool of the present invention is particularly well adapted for use in surgical procedures which require transection of an organ such as the intestine. In operation, the tissue (e.g., intestine) is placed within space 22 defined by tynes 18 and 20. The blade is moved forward along the longitudinal axis x of tynes 18 and 20 by movement of lever 24. As the blade moves forward, it passes through the tissue causing it to be severed. Simultaneously, electrical energy (e.g., radio frequency energy), which may be activated for example by foot switch 32, is delivered to the tool. The electrosurgical current is communicated from the blade 34 to the tissue adjacent the blade and in the vicinity of the incision.

During a cutting procedure the blade should be actuated such that it requires approximately 1.5 to 4.5 seconds to move along its predetermined path to sever tissue. Current should be delivered through the blade to the tissue during the entire cutting procedure.

The application of electrical energy in this manner provides two advantages. Electrosurgical energy is delivered through the blade to adjacent tissue to allow for more effective cutting action, and to promote cauterization and/or tissue fusion which effectively eliminates all or substantially all bleeding which results from the incision. The cauterization and/or fusion effect imparted to tissue minimizes blood loss and increases the safety of the surgical procedure as cauterization occurs at substantially the same time that the incision is made.

In a preferred embodiment of the invention, the electrosurgical tool also includes a staple cartridge 38 which houses a supply of surgical staples to be supplied adjacent the incision. The staples may be deployed in one or more linear rows on either side of the incision to assist in closing the incision and sealing the severed end of the organ. The staples are deployed simultaneously with the cutting action of the blade and the tissue fusion effect imparted by the electrical energy.

One skilled in the art will appreciated that a variety of materials are well suited for the manufacture of the electrosurgical tool of this invention. For example, housing 12 and cartridge 38 may be made from or coated with various non-conducting polymers. The conductive components of the tool may be made of various metals, including surgical grade stainless steel and aluminum.

Although the invention is described with respect to the cutting tool illustrated in Figures 1 through 5, it is understood that various modifications may be made to the illustrated electrosurgical cutting device without departing from the scope of the invention. For example, a variety of blade actuation mechanisms may be used. Also, it is not necessary that tynes 18 and 20 take on the shape and orientation illustrated in the drawings. Moreover, the electrical connection between the generator may be made in ways other than those illustrated and described herein. Thus, the present invention is potentially applicable to virtually all electrosurgical cutting devices in which a cutting blade, moveable along a predetermined path, provides electrosurgical energy to incised tissue simultaneously with the cutting of tissue.

What is claimed is:

1. An electrosurgical cutting device, comprising:

a tool housing including a handle portion;

a cutting element, adjacent the handle portion, having substantially parallel first and second elongate tyne elements which define a tissue engaging space therebetween;

a pathway within the first tyne member which defines a cutting path;

a moveable cutting blade, electrically isolated from the remainder of the tool, said cutting blade being adapted to move from a retracted position, through the pathway in the first tyne to sever tissue;

means for moving the cutting blade through the pathway to effect cutting of tissue; and

selectively operable electrosurgical current supply means for communicating electrical energy through the cutting blade to tissue to cauterize tissue simultaneous with the cutting action of the blade.

2. The device of claim 1 further comprising a ground electrode in electrical communication with the second tyne element, forming a bipolar electrosurgical cutting device.

3. The device of claim 2 wherein the second tyne further comprises a longitudinal pathway which cooperates with the longitudinal pathway of the first tyne to define a cutting pathway for the blade.

4. The device of claim 1, further comprising:

a cartridge means for housing a plurality of surgical staples, said cartridge means disposed on the first tyne member, on a side thereof facing the second tyne member and having a longitudinal groove therein to accommodate passage of the cutting blade;

a means for deploying the staples substantially simultaneously with the cutting action of the blade; and

mandrel means for effecting closure of the staples, the mandrel means being disposed on a side of the second tyne member facing the first tyne member.

5. The device of claim 4 wherein the cartridge means contains dual, linear rows of staple ejection ports disposed on opposite sides of the groove, with surgical staples positioned to be ejected from the ports.

6. The device of claim 4 wherein a ground electrode is in electrical communication with the mandrel means, forming a bipolar electrosurgical device.

7. The device of claim 6 wherein the mandrel means further comprises a longitudinal groove which cooperates with the longitudinal groove of the cartridge means to accommodate passage of the cutting blade.

8. The device of claim 7 wherein the electrical current supply means comprises a conducting electrical wire which communicates electrosurgical energy from a generator to the cutting blade.

9. The device of claim 8 wherein the conducting wire communicates with the blade through a conductive bushing in electrical contact with the blade.

10. The device of claim 7 wherein the electrosurgical energy communicated to the tool is in the radio frequency range.

11. The device of claim 8 wherein the generator is voltage determinative, low impedance electrosurgical generator which supplies electrosurgical energy in the range of 500 to 700 KHz.

12. The device of claim 1 wherein the current of the electrosurgical energy delivered to tissue from the cutting bade is in the range of about 0.5 to 2.0 amps.

13. The device of claim 1 wherein the voltage of the electrosurgical energy delivered to the tissue from the cutting blade is in the range of about 50 to 100 volts RMS.

14. An electrosurgical cutting device, comprising;

a handle means for grasping and manipulating the device;

a cutting portion adjacent to the handle means;

a cutting blade moveable along a cutting path within the cutting portion of the device, the cutting blade being electrically isolated from the remainder of the device and being in electrical communication with a remote generator which provides electrosurgical energy to the blade for delivery to tissue contacted by the blade;

a return electrode associated with a tissue-contacting region of the cutting portion electrically isolated from the cutting blade;

lever means for effecting the movement of the blade along a cutting path within the cutting portion of the device; and

power control means for activating and regulating the electrosurgical energy supplied to the tool.

15. The device of claim 14 wherein the cutting portion comprises substantially parallel tyne elements which extend from the housing means and have a tissue-engaging space therebetween.

16. The device of claim 15 wherein a first tyne element houses the cutting blade and a second tyne element serves as the return electrode.

17. The device of claim 16 wherein a cartridge means for housing a supply of surgical staples is disposed within the first tyne element.

18. The device of claim 17 wherein the lever means further controls the action of a staple ejecting mechanism such that surgical staples are deployed substantially simultaneously with the cutting movement of the blade.

19. The device of claim 18 wherein a means for closing the surgical staples is disposed on the second tyne element.

20. The device of claim 14 wherein the electrosurgical energy supplied by the generator is in the range of about 500 - 700 KHz.

21. The device of claim 14 wherein the current of the electrosurgical energy delivered to tissue through the cutting blade is in the range of about 0.5 to 2.0 amps.

22. The device of claim 14 wherein the voltage of the electrosurgical energy delivered to tissue through the cutting blade is in the range of about 50 to 10 volts RMS.

23. A method of conducting electrosurgical procedures, comprising the steps of:

providing an electrosurgical cutting tool having a retractable blade selectively moveable along a predetermined cutting path, said cutting blade being connected to one pole of a bipolar generator and being electrically insulated from the remainder of the tool;

placing tissue in the cutting path of the cutting blade;

activating the cutting blade such that it passes through and severs the tissue;

providing electrosurgical energy through the cutting blade to tissue adjacent the incision simultaneously with the severing of tissue by the blade such that the affected tissue is cauterized and bleeding associated with the incision is essentially eliminated.

24. The method of claim 23 further comprising the step of deploying a plurality of surgical staples adjacent the incision, simultaneous with the steps of activating the cutting blade and providing electrosurgical energy through the blade to the tissue.

25. The method of claim 24 wherein the current of the electrosurgical energy delivered to tissue through the cutting blade is in the range of 0.5 to 2.0 amps.

26. The method of claim 24 wherein the voltage of the electrosurgical energy delivered to tissue through the cutting blade is in the range of about 50 to 100 volts RMS.

27. The method of claim 24 wherein the time required fo the blade to traverse, cut and cauterize tissue is about 1.5 to 4.5 seconds

AMENDED CLAIMS

[received by the International Bureau on 22 March 1993 (22.03.93); original claims 2 and 6 deleted; original claims 1,3,7,14,16,17, 19 and 23 amended; new claims 28 and 29 added; remaining claims unchanged (7 pages)]

1. (Amended) An electrosurgical cutting device, comprising:

a tool housing including a handle portion;

a cutting element, adjacent the handle portion, having substantially parallel first and second elongate tyne elements which define a tissue engaging space therebetween;

a pathway within the first tyne member which defines a cutting path;

a moveable cutting blade, electrically isolated from the remainder of the tool, said cutting blade being adapted to move from a retracted position, through the pathway in the first tyne to sever tissue;

means for moving the cutting blade through the pathway to effect cutting of tissue;

selectively operable electrosurgical current supply means for communicating electrical energy through the cutting blade to tissue to cauterize tissue simultaneous with the cutting action of the blade; and

a return electrode in electrical communication with the second tyne element and electrically isolated from the cutting blade, forming a bipolar electrosurgical instrument.

2. Cancelled.

3. (Amended) The device of claim 1 wherein the second tyne further comprises a longitudinal pathway which cooperates with the longitudinal pathway of the first tyne to define a cutting pathway for the blade.

4. The device of claim 1, further comprising:

a cartridge means for housing a plurality of surgical staples, said cartridge means disposed on the first tyne member, on a side thereof facing the second tyne member and having a longitudinal groove therein to accommodate passage of the cutting blade;

a means for deploying the staples substantially simultaneously with the cutting action of the blade; and

mandrel means for effecting closure of the staples, the mandrel means being disposed on a side of the second tyne member facing the first tyne member.

5. The device of claim 4 wherein the cartridge means contains dual, linear rows of staple ejection ports disposed on opposite sides of the groove, with surgical staples positioned to be ejected from the ports.

6. Cancelled.

7. (Amended) The device of claim 5 wherein the mandrel means further comprises a longitudinal groove which cooperates with the longitudinal groove of the cartridge means to accommodate passage of the cutting blade.

8. The device of claim 7 wherein the electrical current supply means comprises a conducting electrical wire which communicates electrosurgical energy from a generator to the cutting blade.

9. The device of claim 8 wherein the conducting wire communicates with the blade through a conductive busing in electrical contact with the blade.

10. The device of claim 7 wherein the electrosurgical energy communicated to the tool is in the radio frequency range.

11. The device of claim 8 wherein the generator is voltage determinative, low impedance electrosurgical generator which supplies electrosurgical energy in the range of 500 to 700 KHz.

12. The device of claim 1 wherein the current of the electrosurgical energy delivered to tissue from the cutting bade is in the range of about 0.5 to 2.0 amps.

13. The device of claim 1 wherein the voltage of the electrosurgical energy delivered to the tissue from the cutting blade is in the range of about 50 to 100 volts RMS.

14. (Amended) An electrosurgical cutting device, comprising;

a handle means for grasping and manipulating the device;

a cutting portion, adjacent to the handle means, having substantially parallel first and second elements that define a tissue engaging space therebetween;

a cutting blade disposed within the cutting portion of the device and adapted to be manipulated to sever tissue, the cutting blade being electrically isolated from the remainder of the device and being in electrical communication with a remote generator which provides electrosurgical energy to the blade for delivery to tissue contacted by the blade;

a return electrode associated with a tissue-contacting region of the cutting portion electrically isolated from the cutting blade;

lever means for effecting the movement of the blade within the cutting portion of the device to sever tissue; and

power control means for activating and regulating the electrosurgical energy supplied to the tool.

15. The device of claim 14 wherein the cutting portion comprises substantially parallel tyne elements which extend from the housing means and have a tissue-engaging space therebetween.

16. (Amended) The device of claim 14 wherein the first element houses the cutting blade and the second element serves as the return electrode.

17. (Amended) The device of claim 16 wherein a cartridge means for housing a supply of surgical staples is disposed within the first element.

18. The device of claim 17 wherein the lever means further controls the action of a staple ejecting mechanism such that surgical staples are deployed substantially simultaneously with the cutting movement of the blade.

19. (Amended) The device of claim 18 wherein a means for closing the surgical staples is disposed on the second element.

20. The device of claim 14 wherein the electrosurgical energy supplied by the generator is in the range of about 500 - 700 KHz.

21. The device of claim 14 wherein the current of the electrosurgical energy delivered to tissue through the cutting blade is in the range of about 0.5 to 2.0 amps.

22. The device of claim 14 wherein the voltage of the electrosurgical energy delivered to tissue through the cutting blade is in the range of about 50 to 10 volts RMS.

23. (Amended) A method of conducting electrosurgical procedures, comprising the steps of:

providing a bipolar electrosurgical cutting tool having as an active, energy delivering electrode a retractable blade selectively moveable along a predetermined cutting path, said cutting blade being connected to one pole of a bipolar generator and being electrically insulated from a return electrode disposed on the tool and adjacent the blade;

28. (New) An electrosurgical cutting device, comprising:

a tool housing including a handle portion;

a cutting element, adjacent the handle portion, having substantially parallel first and second elongate tyne elements which define a tissue engaging space therebetween;

a pathway within the first tyne member which defines a cutting path;

a moveable cutting blade, electrically isolated from the remainder of the tool, said cutting blade being adapted to move from a retracted position through the pathway in the first tyne to sever tissue;

means for moving the cutting blade through the pathway to effect cutting of tissue;

a cartridge means for housing a plurality of surgical staples, said cartridge means disposed on the first tyne member, on a side thereof facing the second tyne member and having a longitudinal groove therein to accommodate passage of the cutting blade;

a means for deploying the staples substantially simultaneously with the cutting action of the blade;

mandrel means for effecting closure of the staples, the mandrel means being disposed on a side of the second tyne member facing the first tyne member; and

selectively operable electrosurgical current supply means for communicating electrical energy through the cutting blade to tissue to cauterize tissue simultaneous with the cutting action of the blade.

29. (New) An electrosurgical cutting device, comprising:

a tool housing including a handle portion;

a cutting portion, adjacent the handle portion, having substantially parallel first and second elongate tyne elements which define a tissue engaging space therebetween;

a pathway within the first tyne member which defines a cutting path;

a moveable cutting element, electrically isolated from the remainder of the tool, said cutting element being adapted to move from a retracted position through the pathway in the first tyne to sever tissue;

means for moving the cutting element through the pathway to effect cutting of tissue;

selectively operable electrosurgical current supply means for communicating electrical energy through the cutting element to tissue to cauterize tissue simultaneous with the cutting action of the element; and

a ground electrode in electrical communication with the second tyne element and electrically isolated from the cutting blade, forming a bipolar electrosurgical cutting device.

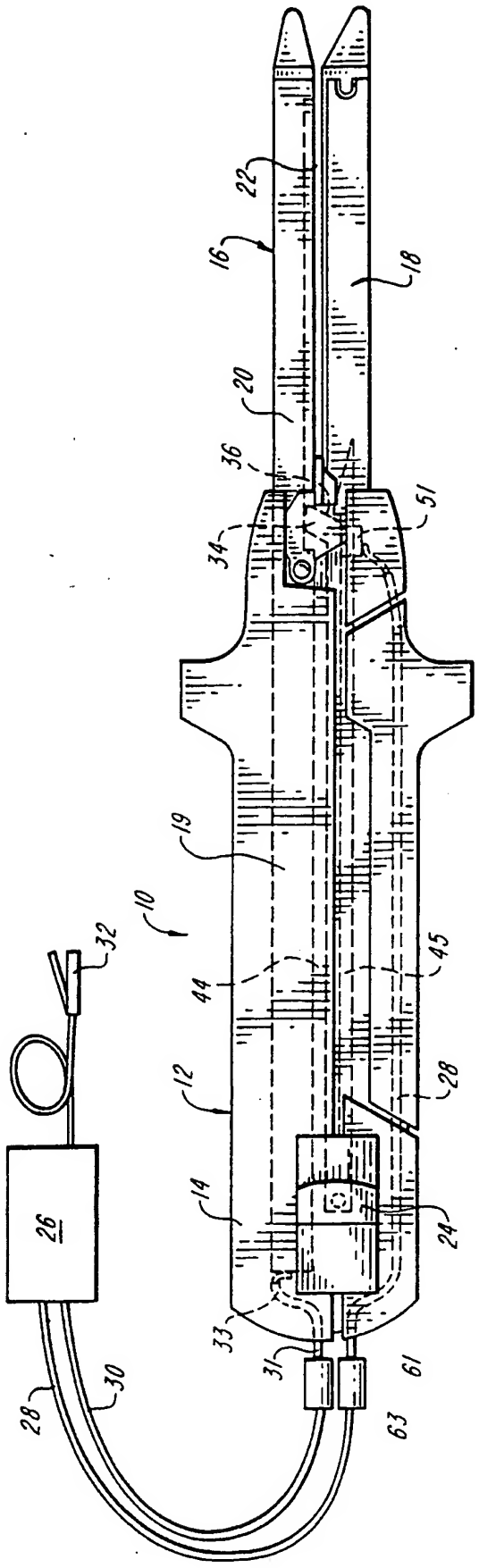

FIG. 1

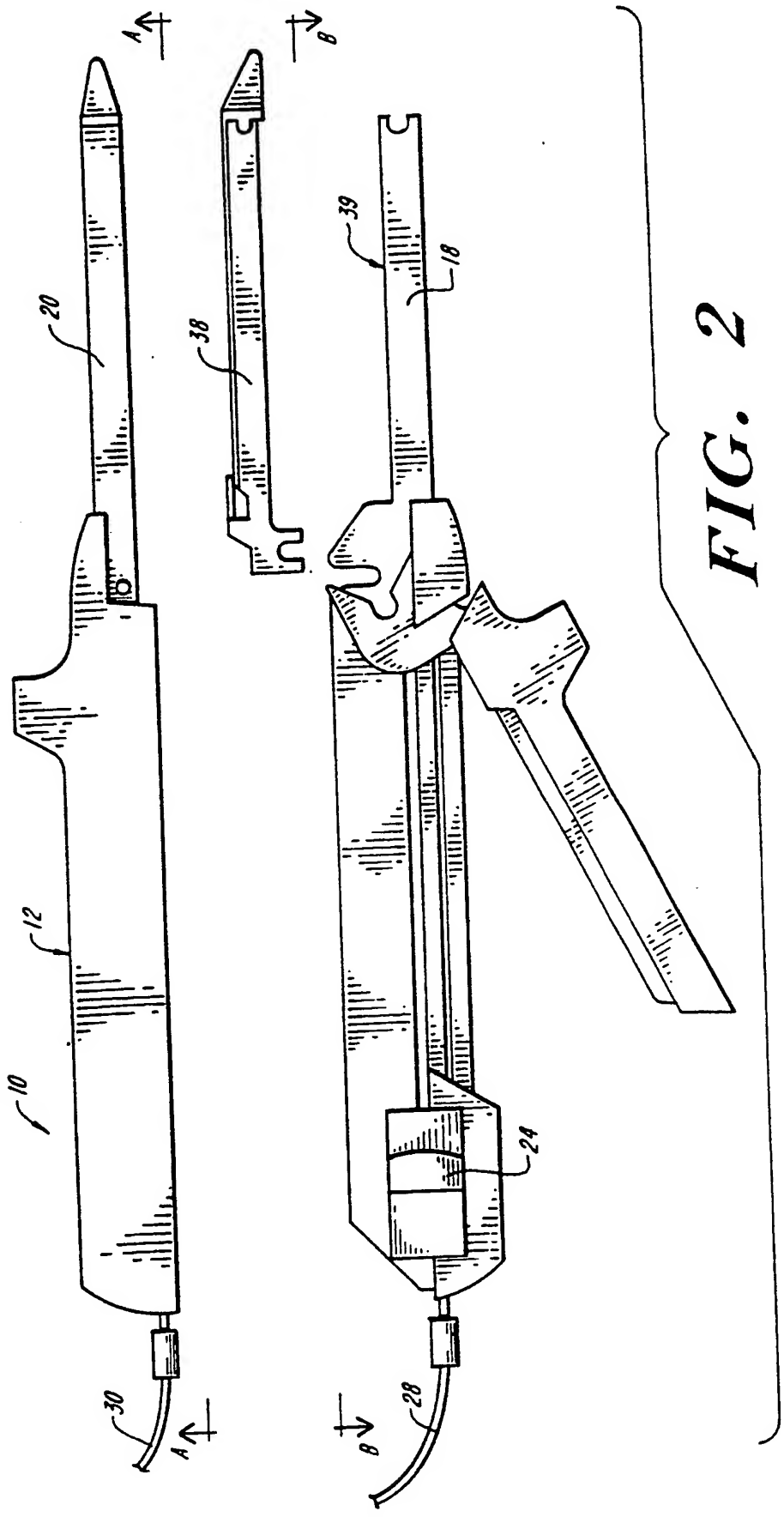

FIG. 2

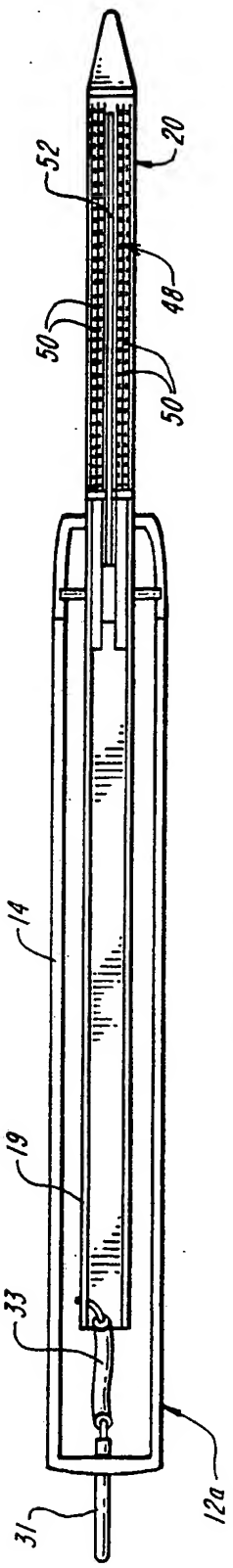
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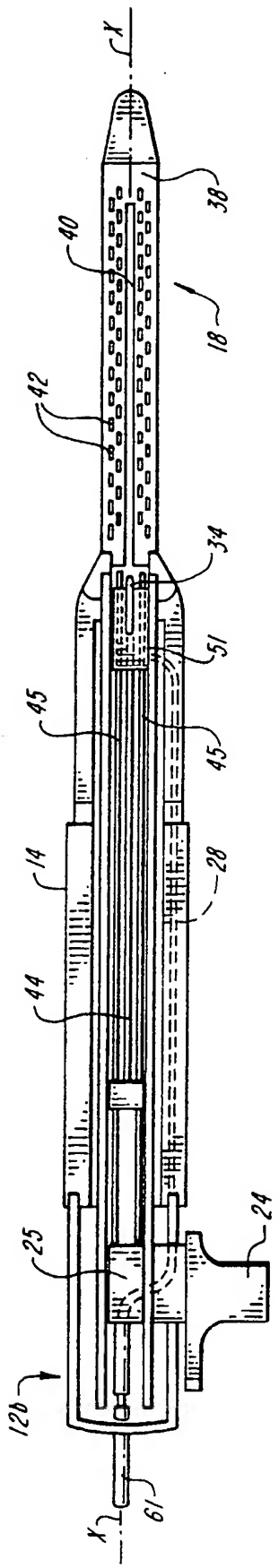
FIG. 4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12b
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X

FIG. 3

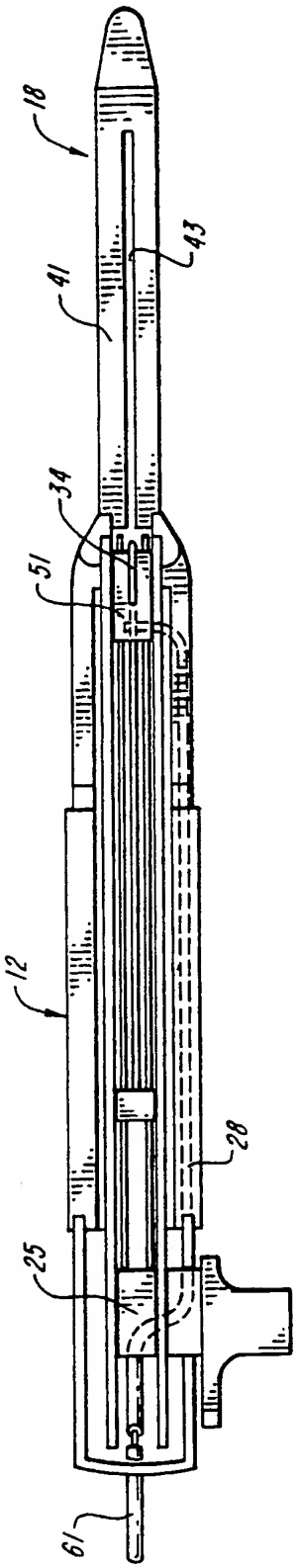

FIG. 5

INTERNATIONAL SEARCH REPORT

PCT/US92/08776

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 17/36
US CL :606/37
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/37 606/139,171,38,45,49,142,143,170

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A, 1,881,250 (Tomlinson) 04 October 1932 See the entire document.	14,23 14,20-23
A	US,A, 4,784,137 (Kulik et al.) 15 November 1988 See the entire document.	1-27
A	US,A, 4,815,465 (Aluarado) 28 March 1989 See the entire document.	1-27
A	US,A, 4,334,539 (Childs et al.) 15 June 1982 See the entire document.	1-27
A	US,A, 3,952,748 (Kaliher et al.) 27 Arpil 1976 See the entire document.	1-27

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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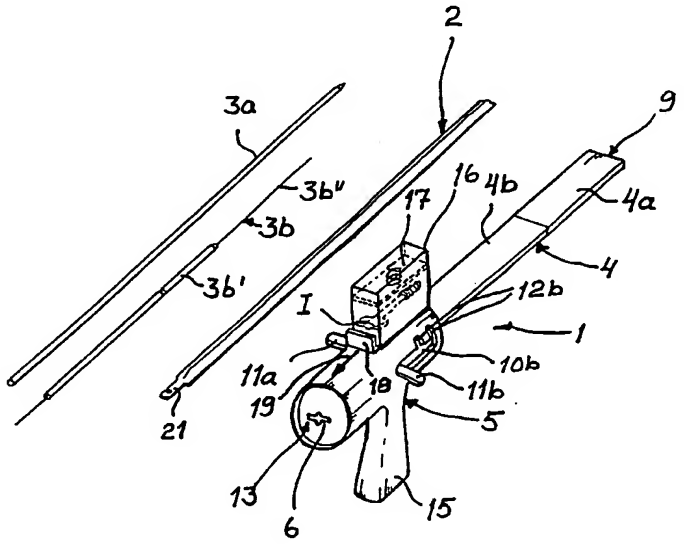
(54) Title: SURGICAL INSTALLATION INSTRUMENT



(57) Abstract

The invention relates to a surgical instrument for installation of a surgical implant in a living tissue, particularly in connection with a surgical operation. The installation instrument comprisng a frame (1) with an installation channel (6), in which the implant (I) is designed to be placed in the beginning of installation, as well as an installation part (2) arranged to be placed in the said installation channel (6) and to convey an external force needed for the installation of the implant (I) to the implant, the frame (1) being placed in connection with the tissue in a manner that the implant is placed in the said tissue when it exits the said installation channel (6) at the installation end (9) of the frame (1). The frame (1) comprises further at least one arresting means (7a, 7b) which in the operational position of the frame (1) has contact with the said tissue in order to arrest the installation end (9) of the frame (1) in position in relation to the tissue during the installation of the implant. The installation part (2) is equipped with means (21) for attaching the installation part (2) into a power transmission part (14) arranged to perform a reciprocating movement, whereby the said reciprocating movement is arranged to be transmitted as a periodical movement of the implant (I) through the installation end (9) of the frame (1) into the tissue.

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Surgical installation instrument

The present invention relates to a surgical instrument for installation of a surgical implant in a living tissue, particularly in connection with a surgical operation. The installation instrument comprises a frame with an installation channel, in which the implant is inserted in the beginning of installation. The instrument comprises further an installation part arranged to be inserted in the said installation channel and to convey an external force needed for the installation of the implant to the implant, the frame being placed in connection with the tissue in a manner that the implant is inserted in the said tissue when it exits the said installation channel at the installation end of the frame.

In this context, living tissue refers particularly to bone, ligament, connective tissue, synovial or joint tissue, muscular tissue, etc. Further, it can be stated that the important fields of applying the invention include corrective surgery of meniscal rupture as well as bone surgery as treatment of bone fractures. The installation instrument of the invention is suitable for use in arthroscopic surgery. In this invention, implant refers to a usually elongated macroscopic piece which is suitable to be surgically installed with a force effective thereon which moves the implant essentially in the direction of its largest dimension into the tissue. Implants of this kind typically include rod-shaped and arrow-shaped implants. As to arrow-shaped implants, reference is made in this context to the publication US-4,873,976 which discloses an arrow-shaped implant and a method for its installation to be used particularly in the repairing surgery of meniscal rupture. The implant is typically manufac-

tured of at least partially bioabsorbable polymer material.

In surgery, it is generally known to use installation instruments, typically manufactured of metal, for installing macroscopic implants, such as rods, hooks, pins, bolts and the like, in living tissues to connect operated or damaged tissues with each other or with other tissues. In such surgical installation instruments, the implant is typically placed at the initial stage either in part or wholly inside an installation channel in the installation instrument and forced from the installation instrument into the tissue by tapping manually with a hammer a special, typically piston-like installation part which conveys the force generated with the hammer to the implant and thus forces the implant to penetrate into the tissue. It is also known to use an application whereby the implant is forced into the tissue by one powerful, quick stroke effected on the implant e.g. mechanically, pneumatically, hydraulically or electromagnetically.

However, the surgical installation instruments of prior art used for installing macroscopic implants into a tissue have certain disadvantages. If the surgeon uses a manual instrallation instument, he/she needs both of his/her hands for controlling the instrument. By one hand the surgeon must support the frame of the surgical implant, wherein the surgical implant is inserted at least partly in the beginning of the installation operation. By the other hand the surgeon must tap the hammer or a corresponding tool, thus directing the force required for the transmission of the implant and conveyed by an installation part into the implant. Consequently, the surgeon cannot by his/her own hands keep in position that part or parts of the tissue which he/she will attach to each other with the implant. Thus, the surgeon must usually have

an assistant who keeps the parts of the tissue in position. As a result, the direct feel of the surgeon to the reactions of the tissue is essentially diminished as the operation proceeds. If the surgeon alternatively uses an installation instrument which forces the implant by one stroke into the tissue, his/her control over the installation procedure is very poor also in this case, because e.g. the direction or position of the implant thus cannot be changed as the installation operation proceeds, and the installation operation cannot be stopped after the implant has been triggered.

It is the object of this invention to present a surgical installation instrument of a new kind for use in the installation of macroscopic implants, deprived of the disadvantages of installation instruments of prior art as well as of factors delimiting the safety of patients. For achieving this aim, the installation instrument according to the invention is primarily characterized in that the said installation part comprises means for connecting the installation part to a power transmission part arranged to perform a reciprocating movement, whereby the said reciprocating movement is arranged to be transmitted as a periodical movement of the implant from the installation channel through the installation end of the frame into the tissue.

Application of the surgical installation instrument in the manner described above provides several advantages over the instruments of prior art.

Using an installation instrument of the invention, the surgeon can install an implant into a tissue by one hand, whereby he/she can by his other hand keep in position those parts of the tissue, through which the implant is intended to be forced. The surgeon can

thus control the installation operation better than with present methods, including correcting the position of the tissues during the installation operation when necessary. Also, the penetration of the implant effected by successive, quick strokes enables the surgeon to control the installation operation better than before, because he/she can e.g. change the direction of the installation instrument and/or the implant during the installation operation or interrupt the operation if necessary. This may be required e.g. in a case when the tissues to be attached to each other are displaced for any reason during the operation. The advantages of the installation instrument exerting quick reciprocating or vibrational movement can have the following theoretical basis: According to the viscoelastic theory, the modulus of viscoelastic material increases with an increase in the velocity of dynamic stress. In practice, this means that when an arrow-shaped implant is slowly penetrated into a viscoelastic connective tissue such as meniscal tissue, the meniscal tissue reacts as a soft material, yielding and tending to bend away from the implant penetrating into it. On the other hand, when the implant is vibrated step-by-step into the tissue utilizing a reciprocating movement by quick strokes of the installation instrument, the meniscal tissue will not react fast enough to the movement of the arrow-shaped implant in the manner of a soft material, but in a way it reacts as a hard material, not yielding with the forward movement of the implant anywhere near the extent as in manual penetration or stroke. The implant thus penetrates the meniscal tissue (or a preliminary hole made in it) easily without causing extensive transformation of the surrounding tissue.

In a particularly advantageous embodiment, the frame of the installation instrument comprises further at least one arresting means which is in the operational

position of the frame, in which case the installation part is inserted inside the installation channel, in contact with the said tissue in order to arrest the installation end of the frame in position in relation to the tissue during installation of the implant. As the frame can be locked in the installation end by the arresting means into the tissue for the time of the operation, the surgeon can secure the correct position of the installation channel before the actual phase of installing the implant.

Further, according to a preferred embodiment of the invention, at least one arresting means in the surgical installation instrument is arranged to be movable and lockable in relation to the frame, wherein the said arresting means in the non-operational position is placed inside the installation end of the frame and in the operational position protrudes from the installation end of the frame. In this application, it is possible to place the arresting means inside a tissue, particularly a soft tissue, in a way required by the surgical operation and the dimensions of the tissue in question. The arresting means can be advantageously locked at different penetration depths in relation to the frame in its operational position. For this purpose, the frame can be equipped with several locking means cooperating with a transfer and locking means placed in the arresting means and preferably controlled manually, which can be locked in position for locking the arresting means in a desired operational penetration depth.

Further, according to another preferred embodiment of the invention, the installation instrument comprises further at least one needle-like element with a cross-section at least partly formed in a manner that the needle-like element with a cross-section at least partly formed in a manner that the needle-like element

can be placed via the installation channel or a part thereof to bypass the installation end of the frame in order to make a preliminary hole or a like in the tissue before the installation of the implant, the installation end of the frame being placed in the installation position of the implant and arrested by at least one arresting means. This application provides the advantage of a smaller force required for the series of strokes by the installation part on the implant. As a natural consequence, the risk of an implant to be directed into an incorrect position and to be damaged is substantially reduced, because the forces effective upon it during installation are reasonable. This embodiment is particularly advantageous in connection with operations on tough fibrous tissues, such as meniscus, in which the margin of error is very small.

Further, according to still another advantageous embodiment, the frame of the installation instrument is at least partially formed of a transparent material.

Installation instruments of prior art are manufactured of metal material, particularly stainless steel. For this reason, these installation instruments have the disadvantage of not enabling the surgeon to evaluate visually the progress of the installation of the instrument and the condition of the implant. In particular, lack of visual contact with at least that part of the installation instrument where the implant is situated, i.e. the installation end of the installation frame of the instrument, complicates arthroscopic operations in which an operation is performed inside a joint by entering the installation instrument into the arthral chamber through a small incision and by controlling the stages of the operation by means of a special arthroscopic instrument which is entered into the arthral chamber either through

the same or another small incision. Consequently, the surgical installation instrument of the present invention can also be used to avoid this adverse factor present in installation instruments of prior art and thus to further increase reliability and safety of the installation to the patient.

Some advantageous embodiments of the surgical installation instrument of the invention are further presented in other appended, dependent claims.

In the following description, the surgical installation instrument of the invention will be illustrated further with reference to the embodiments shown in the appended drawings. In the drawings,

Fig. 1 shows a schematic perspective view of the surgical installation instrument, its first embodiment,

Fig. 2 illustrates the cross-section of the frame of the installation instrument shown in Fig. 1 in its longitudinal direction,

Fig. 3 shows a perspective view of a second embodiment of the surgical installation instrument, where the installation part is fixed in connection with a power transmission element,

Fig. 4 illustrates the cross-section of the frame of the installation instrument shown in Fig. 3 in its longitudinal direction, and

Figs. 5a-d illustrate schematically the phases of installation of an implant, particularly an arrow-shaped implant, into the meniscus.

With reference to Fig. 1, the installation instrument of the invention comprises as main parts a frame 1 and an installation part 2. Figure 1 illustrates also two needle-like elements 3a, 3b of the surgical installation instrument.

The frame 1 comprises a combination of an elongated installation frame 4 and an operational frame 5. The frame 1 is penetrated by an installation channel 6 whose cross-sectional form corresponds to the shape of the outer surface of the implant I as seen in the direction of the longitudinal axis of the implant. In the embodiment shown, the installation frame is made to have a flat cross-sectional form, e.g. a rectangular or oval form. The installation channel 6 is situated centrally in the direction of the greater dimension of the flat cross-sectional form in a way that arresting means 7a, 7b are located on both sides thereof in the same direction. The arresting means can be fixedly mounted or attached, or they are placed in corresponding arresting channels 8a, 8b in the frame, which extend in the direction of the installation channel. In the non-operational position, the arresting means, which are rod-like elements with a sharpened head and a circular cross-sectional form, are inside the installation end 9 or the frame 1. At the point of the arresting means, there is a longitudinal groove 10a, 10b on both sides of the operational frame 5, with protruding transfer and locking means 11a, 11b connected with the arresting means.

In the embodiment shown above, a transverse grooving 12a, 12b has been formed in the grooves 10a, 10b which is perpendicular to the longitudinal direction of the said grooves 10a, 10b and in which the transfer and locking means 11a, 11b can be placed when the arresting means is moved into the operational position

in the longitudinal direction of the arresting channel 8a, 8b and thus to protrude from the installation end 9 of the frame 1. The arresting means are locked by moving the said transfer and locking means 11a, 11b around the longitudinal axis of the arresting means into a desired groove of the transverse grooving 12a, 12b.

As mentioned above, the other end of the installation channel 6 is placed at the supply end 13 of the operational frame in a manner that that the installation part 2 can, fixed with the power transmission part 14 (Fig. 3), be inserted in the installation channel.

The operational frame is further equipped with a handle 15.

In the application shown in Fig. 1, the operational frame 5 further comprises a cassette or box 16 which can be changed in connection with the operational frame. A suitable number of implants I can be placed within the box 16 in advance, one being illustrated inside the box 16 with broken lines. In the embodiment shown, the implant I is an arrow-shaped element having a head and a stem at opposite ends of a body. The head comprises a scutellate or corresponding arresting structure, and the radial dimension of the stem is formed to exceed that of the body. In connection with a surgical operation on e.g. a meniscal rupture, as illustrated particularly in Fig. 5d, the head penetrates the meniscus at least partially, and the stem remains outside the meniscus to prevent an unintentional movement of the implant in the direction of installation. On the other hand, the scutellate or corresponding structure of the head cooperates with the stem, exerting a compressing force on the meniscus, particularly the rupture. This contributes to the

healing of the meniscus. In this connection, it should be pointed out that although the invention is illustrated with an example which is applicable particularly in surgical operations of the meniscus, it is clear that the surgical instrument of the present invention can be equally well applied in bone surgery, particularly in surgical operations on bone fractures, in connective tissue surgery and other surgery of the tissues of the musculosceletal system. Further, with reference to Fig. 1, the box 16 can comprise a spring-loaded plunger 17 which keeps the implants I in such an order in the box 16 that upon pulling a loading device 18 between the box 16 and the operational frame 5 e.g. in the direction of arrow 19, the next implant I is moved from the box 16 into the installation channel 6 within the operational frame, as shown schematically in Fig. 2. From this position, the implant I can, e.g. by using the installation part 2, be transferred to the installation end 9 of the installation channel.

In an advantageous manner, the surgical installation instrument of the invention is made to be at least partly transparent. In the embodiment of Fig. 1, the part at the installation end 9 of the installation frame 4 is made transparent. This transparent part 4a of the installation frame 4 can be advantageously manufactured as a disposable part which can be attached with snap-in fixing means to the stationary part 4b of the installation frame mounted on the operational frame 5. The snap-in fixing means are shown by the reference numeral 20 in Fig. 2. The transparent part 4a can be manufactured of a transparent polymer, copolymer or a polymeric mixture. Also ceramic materials are feasible. The transparent part 4a naturally comprises a part corresponding to the cross-sectional form of the installation channel as well as parts corresponding

to the arresting channel, whereby it is functionally fully compatible with the frame 1.

Figure 1 further illustrates the installation part 2 pertaining to the surgical instrument of the invention. This is an elongated rod-like formed piece with a cross-sectional form perpendicular to the longitudinal direction corresponding preferably to the cross-sectional form and size of the installation channel 6 of the frame 1. The length of the installation part is elected so that, connected with a power transmission part 14, it can act on the implant in the installation channel, particularly the stem, for the entire length of the installation channel. The other end part of the installation part 2 is equipped with a means 21 for attaching the installation part into the power transmission part 14 (Fig. 3). The reciprocating movement of the power transmission part 14 is arranged in a way that the installation part 2 moves backward and forward in its longitudinal direction (arrow L in Fig. 3).

Figure 3 illustrates an embodiment of the frame 1 where the implant is fed into the installation channel through an opening in the supply end 13 in the installation channel. Using the installation part 2 coupled with the power transmission part 14, the implant is entered into the installation end 9 of the frame 1 in the installation channel. The power transmission part 14 can be operated on a pneumatic, hydraulic and/or electromagnetic principle. The power transmission part 14 shown in Fig. 3 is arranged to work pneumatically, whereby it has a connecting means 14a for conveying compressed air into a piston arrangement inside the frame 14b of the power transmission part 14. Power transmission parts of this kind are available in different commercial applications, e.g. as reciprocating surgical bone saws, which can be applied with

minor technical modifications for use in combination with a surgical installation instrument of this invention. As an example of such power transmission parts, products marketed under the trademark HALL^{R} can be named. Power transmission parts of this kind as well as their socket structures, in which the attaching means 21 of the installation part 2 (Fig. 1) is attached, are obvious to an artisan in the field and consequently not described more closely in this context.

Figure 4 shows an alternative application for combining the installation frame 4, which is preferably transparent, and the operational frame 5. The installation frame 4 is entirely formed of a transparent material, and its end is equipped with a flange 22 whereby it is attached (broken lines in Fig. 4) e.g. with a screw fastening to the end of the operational frame 5. An advantage of this arrangement is that installation frames 4 of different shapes can be used in connection with the same operational frame 5. It is a generally known fact that curved or bended forms of the installation frame 4 may be required in certain surgical operations in order to get at the tissue to be operated on. Consequently, a solution of this kind can broaden the field of use of the surgical installation instrument. Naturally in these cases flexibility is required of the material of the arresting means so that they can adjust to the shape of the installation frame 4.

Particularly Figs. 5a-5d illustrate schematically the phases of a surgical operation performed using a frame shown particularly in Figs. 3 and 4. The operation shown in Fig. 5 is a surgical repairing operation of a rupture R of the meniscus NK. This is performed preferably by arthroscopy. In the first phase shown in Fig. 5a, the arresting means 7a, 7b are pushed into the operational position by using the transfer

and locking means 11a, 11b, whereby the said arresting means can extend over the rupture. In this manner, the installation end 9 of the frame 1 is locked in position and at the same time the rupture R is immobilized and thus controlled. In the next phase according to Fig. 5b, a needle-like element 3a is entered via the installation channel 6 into the meniscus in order to make a preliminary hole. Figure 5b illustrates the use of a needle-like element 3a, but as shown particularly in Fig. 5c, also a needle-like element 3b of Fig. 1 can be used. It comprises two needle-like elementss, one inside the other, of which the outer one 3b' has a larger diameter and inside it is a relatively thin needle-like element 3b" by which the preliminary hole is lengthened after the outer needle-like element 3b' has substantially reached the center of the meniscus and passed the rupture, all the way through the meniscus. Thus a preliminary hole ER is formed as shown in Fig. 5c, comprising a part ER1 with a wider diameter and a part ER2 with a smaller diameter. The diameter of the needle-like element can correspond to the diameter of the body of the implant I, whereby the needle-like element can be moved in the installation channel along the wider middle section of the installation channel. This wider middle section is shown by the reference numeral 6a in Fig. 4. Particularly for the wider wing structure of the stem of the implant I, the installation channel 6 is provided with widenings shown by the reference numeral 6b in Fig. 4. Further, Fig. 5c illustrates the placement of the implant in the installation channel 6 all the way to the installation end 9 of the installation frame 4 using the installation part 2 which is coupled with the power transmission part 14. The implant I is pressed via the preliminary hole ER through the meniscus into a position shown in Fig. 5d. In this phase, the advantages of the surgical installation instrument of the present invention are obvious. The

arresting means 7a, 7b secure that the frame 1 is kept in position. The preliminary hole ER facilitates the installation of the implant. The transparent installation frame 4 provides immediate visual control of the position of the implant in the installation frame also during arthroscopy. Further, the most important operational advantage in this phase is the fact that the surgeon, while maintaining contact with the stem of the implant I with the head of the installation part 2, can observe the implant as it proceeds into the preliminary hole and stop the installation of the implant if necessary. Thus the implant can be installed into the tissue in stages by utilizing the reciprocating movement of the installation part and the simultaneous movement in the installation channel feeding the installation part.

It is obvious that the advantages presented above apply also to many other surgical operations than meniscal operations.

The installation instrument of the invention can be modified even to a high degree. One particular alternative for a frame, especially a transparent installation frame, is to fix the arresting means in connection with the transparent frame in a manner that they protrude from the installation end 9. Thus the arresting means 11a and 11b which can be moved and locked in relation to the frame 1 can be eliminated from the frame 1. It is also obvious that there can be only one, or more than two of the arresting means 7a, 7b placed in the same frame 1 to be moved and locked in relation to the frame 1, or to the transparent installation frame, protruding from the installation end 9 of the installation frame.

Obviously, the dimensions and shape of the surgical installation instrument can vary even considerably;

only a few applicable alternatives are shown in the appended drawings. In the embodiment shown in the drawings, the following dimensions can be brought up within the basic dimensions. The total length of the installation frame 4 can vary between 20 and 200 mm. The width and thickness of the flat cross-section of the installation frame 4 can be typically 3 to 6 mm and and 1 to 3 mm, respectively. The length of the operational frame 5 can be 20 to 120 mm, whereby the total length of the frame 1 varies between 40 and 320 mm. The penetration depth of the arresting means can be chosen by the transverse grooving to be e.g. 5-10 mm. The arrow-shaped implant used e.g. in meniscal surgery has a length of ca. 14 mm. The diameter of the body is ca. 1.5 mm, and the maximum radial dimension of the stem is 3 mm, the dimension of the stem length of the wing in the axial direction being ca. 1.5 mm.

One very important detail, it can be mentioned that according to practical measurements, good penetration of the implant into the meniscal tissue is achieved when the maximum rate of a single stroke of the vibrating movement is at least 300 m/min and the frequency of the strokes is higher than 1000/min (ca. 17/s), preferably ca. 10000-20000/min (ca. 170-340/s). If the stroke rate is in the order of 50 to 150 m/min, which is a typical stroke rate when slow vibration is performed manually by hitting a cylindrical piston with a suitable hammer, the piston conveying the stroke to the implant, the rate of the stroke is thus so low that the meniscal tissue reacts in a manner of a soft material, yielding and bending, whereby the implant does not properly penetrate into the tissue.

As to the implant presented in this invention, particular reference is made to the parallel patent application "Surgical implant" of the same applicant, where the structure of the implant is described in detail.

Claims:

1. Surgical instrument for installation of a surgical implant in a living tissue, particularly in connection with a surgical operation, the installation instrument comprising a frame (1) with an installation channel (6), in which the implant (I) is inserted in the beginning of installation, as well as an installation part (2) arranged to be inserted in the said installation channel (6) and to convey an external force needed for the installation of the implant (I) to the implant, the frame (1) being placed in connection with the tissue in a manner that the implant is inserted in the said tissue when it exits the said installation channel (6) at the installation end (9) of the frame (1), **characterized** in that the said installation part (2) comprises means (21) for connecting the installation part (2) to a power transmission part (14) arranged to perform a reciprocating movement, whereby the said reciprocating movement is arranged to be transmitted as a periodical or movement of the implant (I) from the installation channel (6) through the installation end (9) of the frame (1) into the tissue.

2. Surgical installation instrument according to claim 1, **characterized** in that the frame (1) comprises further at least one arresting means (7a, 7b) which is in the operational position of the frame (1), the installation part (2) being inserted inside the installation channel (6), in contact with the said tissue in order to arrest the installation end (9) of the frame (1) in position in relation to the tissue during the installation of the implant.

3. Surgical installation instrument according to claim 1 or 2, **characterized** in that the said at least one arresting means (7a, 7b) is arranged to be movable and lockable in relation to the frame (1),

wherein the said arresting means in the non-operational position is placed inside the installation end (9) of the frame (1) and, brought into the operational position, protrudes from the installation end (9) of the frame (1).

4. Surgical installation instrument according to any of claims 1 to 3, **characterized** in that the arresting means (7a, 7b) is stationary in relation to the frame (1) and protrudes from the installation end (9) of the frame (1).

5. Surgical installation instrument according to any of claims 1 to 4, **characterized** in that the installation channel (6) is arranged to penetrate the frame (1) in its longitudinal direction, and that the frame (1) comprises an arresting channel (8a, 8b) extending in the longitudinal direction of the said installation channel (6) to the installation end (9) of the frame, in which the rod-like arresting means (7a, 7b) is arranged to move in the longitudinal direction of the arresting channel (8a, 8b) and to protrude from the installation end (9) of the frame (1) in the operational position of the arresting means (7a, 7b).

6. Surgical installation instrument according to any of claims 1 to 3 or 5, **characterized** in that the frame (1) comprises a combination of an elongated installation frame (4) and an operational frame (5), whereby the operational frame (5) comprises means (11a, 11b, 12a, 12b) for moving the arresting means (7a, 7b) in relation to the frame (1) and to lock it stationarily in relation to the frame (1), particularly in the operational position of the arresting means (7a, 7b).

7. Surgical installation instrument according to any of claims 1 to 3, 5 or 6, **characterized** in that

the installation frame (4) has a flat cross-sectional form, whereby the said installation channel (6) is situated centrally in the direction of the greater dimension of the flat cross-sectional form in relation to two arresting means (7a, 7b) which are located on both sides thereof and placed to be movable in their longitudinal direction into corresponding arresting means (8a, 8b), both arresting means (7a, 7b) having corresponding means (11a, 11b, 12a, 12b) for moving and locking the arresting means (7a, 7b) in relation to the frame (1).

8. Surgical installation instrument according to any of claims 1-3 or 5-7, **characterized** in that the operational frame (5) comprises one or more locking means (12a, 12b), and that the arresting means (7a, 7b) are provided with a manually controllable transfer and locking means (11a, 11b) placed in connection with the the operational frame (5) and transferrable along a groove (10a, 10b) connected with the locking means (12a, 12b) to achieve contact between said transfer and locking means (11a, 11b) and said locking means (12a, 12b) in order to achieve locking between the frame (1) and the arresting means (7a, 7b).

9. Surgical installation instrument according to any of claims 1 to 8, **characterized** in that the frame (1) comprises a handle (15) located preferably in the operational frame (5).

10. Surgical installation instrument according to claim 1, **characterized** in that the reciprocating movement of the power transmission part (14) is arranged to be effected by a pressurized medium, such as pneumatically or hydraulically, and/or electromagnetically.

11. Surgical installation instrument according to any of claims 1 to 3, **characterized** in that it com-

prises further at least one needle-like element (3a, 3b) with a cross-section at least partly formed in a manner that the needle-like element can be placed via the installation channel (6) or a part (6a) thereof to bypass the installation end (9) of the frame (1) in order to make a preliminary hole (ER) or a like in the tissue before the installation of the implant (I), the installation end (9) of the frame (1) being placed in the installation position of the implant (I) and arrested by at least one arresting means (7a, 7b).

12. Surgical installation instrument according to claim 11, **characterized** in that a series of the said needle-like means (3a, 3b) is arranged in connection with the installation instrument in a way that the cross-sectional diameter of the parts in the series is of varying size, particularly in order to form preliminary holes (ER) of varying size and extending to different depths in the tissue.

13. Surgical installation instrument of any of claims 1 to 8, **characterized** in that the frame (1) is at least partially formed of a transparent material.

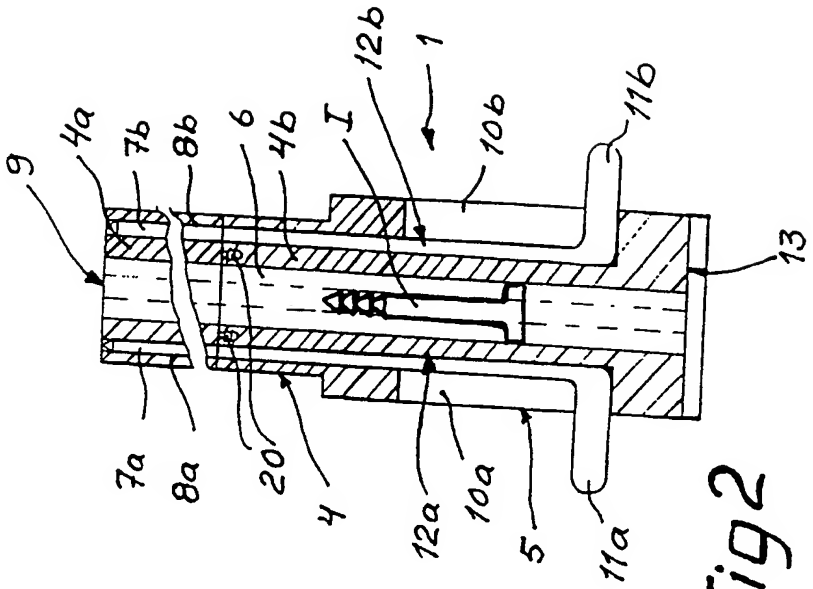
14. Surgical installation instrument according to claims 6 and 13, **characterized** in that the installation frame (4) of the frame (1), or at least the part (4a) close to the installation end (9) thereof, is at least partially manufactured of a transparent material.

15. Surgical installation instrument according to claim 13 or 14, **characterized** in that the transparent part of the frame (1) or the installation frame (4) is arranged to be disposable, and that the frame (1) is equipped with attaching means for receiving the attaching means or the like (20, 22) of the disposable transparent part.

16. Surgical installation instrument according to any of claims 13 to 15, **characterized** in that the installation frame (4) is entirely transparent.

17. Surgical installation instrument according to any of claims 4 or 13 to 16, **characterized** in that the arresting means (7a, 7b) is arranged to be stationary in connection with the installation frame (4) manufactured of a transparent material or in connection with a part (4a) of the installation frame (4) manufactured of a transparent material.

18. Surgical installation instrument according to claim 1, **characterized** in that the maximum rate of the stroke movement is at least 300 m/min and the frequency of the strokes is higher than 1000/min, preferably ca. 10000-20000/min.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7b
8b
6
4b
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5
11a

Fig2

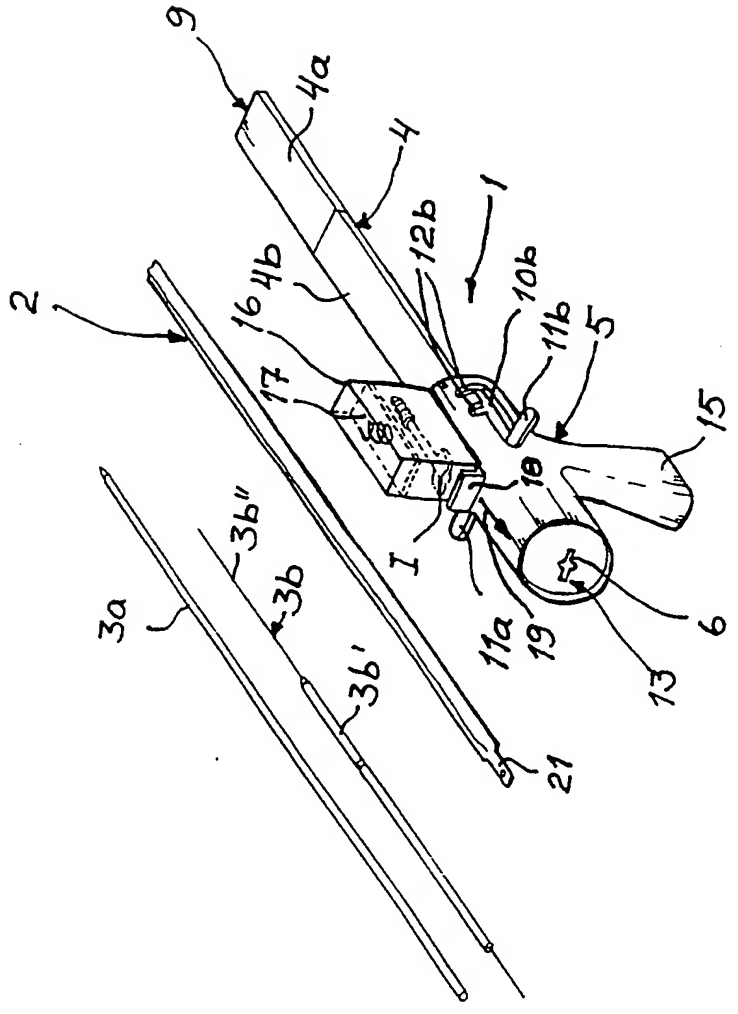
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Fig1

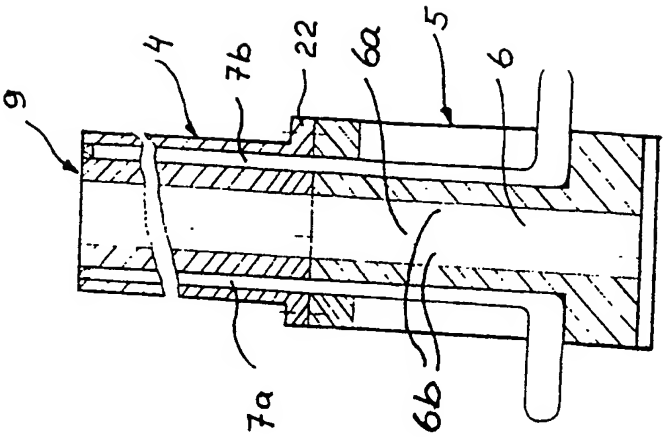

Fig 4

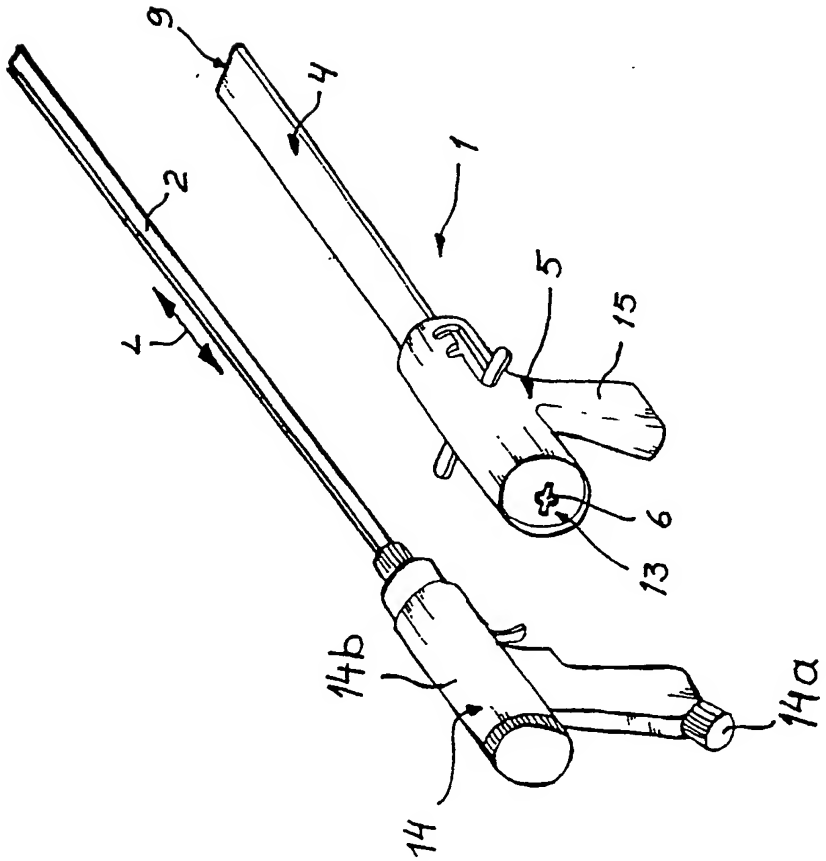

Fig 3

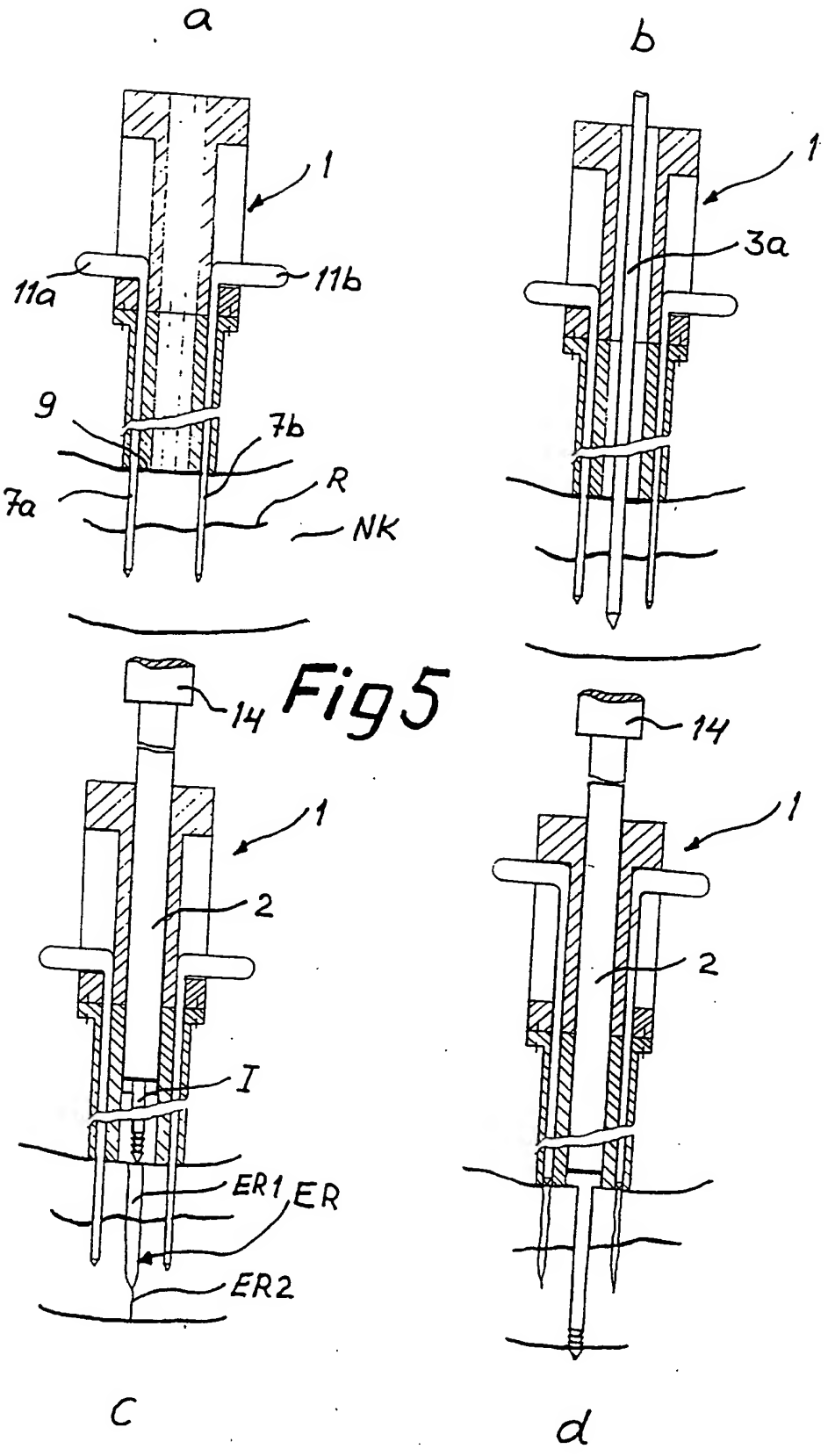

Fig 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 93/00015

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61B 17/068, A61B 17/56
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC5: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5059206 (T.F. WINTERS), 22 October 1991 (22.10.91), figures 26-27 --	1-18
A	US, A, 4873976 (S.N. SCHREIBER), 17 October 1989 (17.10.89), figure 12, abstract --	1-18
A	EP, A2, 0130784 (MINNESOTA MINING AND MANUFACTURING COMPANY), 9 January 1985 (09.01.85), abstract -- --------	1-18

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
28 April 1993	03 -05- 1993
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Hans Presto Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

31/03/93

International application No.
PCT/FI 93/00015

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 5059206	22/10/91	NONE	
US-A- 4873976	17/10/89	AU-A- 4066785	24/09/85
		EP-A- 0174361	19/03/86
EP-A2- 0130784	09/01/85	SE-T3- 0130784	
		AU-B- 570469	17/03/88
		AU-A- 2897084	03/01/85
		CA-A- 1237353	31/05/88
		JP-B- 4054462	31/08/92
		JP-A- 60020872	02/02/85
		US-A- 4540110	10/09/85

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